

# **EXHIBIT A**

**ABBOTT LABORATORIES,**  
Plaintiff-Appellant,  
and

**Astellas Pharma, Inc.,** Plaintiff-  
Appellant,

v.

**SANDOZ, INC.,** Defendant-Appellee,  
and

**Sandoz GMBH,** Defendant,  
and

**Teva Pharmaceuticals USA, Inc. and**  
**Teva Pharmaceutical Industries,**  
**Ltd.,** Defendants-Appellees,  
and

**Ranbaxy Laboratories, Ltd. and**  
**Ranbaxy, Inc.,** Defendants,  
and

**Par Pharmaceutical Companies, Inc.**  
**and Par Pharmaceutical,**  
Defendants.

**Lupin Limited,** Plaintiff/Counterclaim  
Defendant-Appellee,  
and

**Lupin Pharmaceuticals, Inc.,**  
Counterclaim Defendant-  
Appellee,

v.

**Abbott Laboratories,**  
Defendant/Counterclaimant-Appellant,  
and

**Astellas Pharma, Inc.,**  
Defendant/Counterclaimant-Appellant.

Nos. 2007-1400, 2007-1446.

United States Court of Appeals,  
Federal Circuit.

May 18, 2009.

**Background:** Competitor brought action against patent licensee seeking declaratory judgment of non-infringement of patent for crystalline cefdinir. The United States

District Court for the Eastern District of Virginia, Robert E. Payne, J., 484 F.Supp.2d 448, construed patent, and entered summary judgment of noninfringement, 491 F.Supp.2d 563. Licensee appealed. In another action, licensee brought patent infringement action against competitors. The United States District Court for the Northern District of Illinois, Wayne R. Andersen, J., 486 F.Supp.2d 767, construed patent, and denied licensee's motion for preliminary injunction. Licensee appealed. Appeals were consolidated.

**Holdings:** Following sua sponte order of review en banc, the Court of Appeals, Rader, Circuit Judge, held that:

- (1) patent was limited to "Crystal A" form of compound;
- (2) process terms in product-by-process claims serve as limitations in determining patent infringement; overruling *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565;
- (3) phrase "obtainable by" introduced limiting process steps;
- (4) patent's claims could not be extended under doctrine of equivalents to embrace known but unclaimed subject matter; and
- (5) district court did not abuse its discretion in denying preliminary injunction.

Affirmed.

Newman, Circuit Judge, dissented in part and filed opinion in which Mayer and Lourie, Circuit Judges, joined.

## 1. Patents $\S$ 167(1)

Patent's specification provides necessary context for understanding patent's claims, and is always highly relevant to claim construction analysis.

## 2. Patents $\S$ 167(1.1)

When consulting patent specification to clarify meaning of claim terms, courts

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the Eastern District of E. Payne, J., 484 construed patent, and endgment of noninfringement, licensee brought action against competitor District Court for District of Illinois, Wayne R.

F.Supp.2d 767, denied licensee's motion for summary judgment. Licensee appealed. District Court affirmed consolidated.

On sua sponte order of the Court of Appeals, the court held that:

related to "Crystal A" form

in product-by-process limitations in determining infringement; overruling *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565;

able by" introduced limitations;

could not be extended to encompass unclaimed subject

and not abuse its discretion in preliminary injunction.

Judge, dissented in part in which Mayer and others joined.

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The court provides necessary understanding of patent's highly relevant to analysis.

1)  
The patent specification of claim terms, courts

must take care not to import limitations into claims from specification.

### 3. Patents $\Rightarrow$ 167(1.1)

When patent specification describes single embodiment to enable invention, court will not limit broader claim language to that single application unless patentee has demonstrated clear intention to limit claim scope using words or expressions of manifest exclusion or restriction.

### 4. Patents $\Rightarrow$ 167(1.1)

Claims cannot enlarge what is patented beyond what inventor has described as invention.

### 5. Patents $\Rightarrow$ 167(1.1)

Court may reach narrower construction of patent, limited to embodiments disclosed in specification, when claims themselves, specification, or prosecution history clearly indicate that invention encompasses no more than that confined structure or method.

### 6. Patents $\Rightarrow$ 168(2.1)

Doctrine of patent prosecution disclaimer only applies to unambiguous disavowals.

### 7. Patents $\Rightarrow$ 101(4)

Term "crystalline," as used in patent for antibiotic crystalline cefdinir, was limited to "Crystal A" form of compound, where Crystal A was only embodiment described in specification, specification stated that Crystal A showed its distinguishing peaks at seven particular powder X-ray diffraction (PXRD) angles enumerated in claim, prosecution history showed clear and intentional disavowal of claim scope beyond Crystal A, and patent offered no suggestion that recited processes could produce non-Crystal A compounds, even though other types of cefdinir crystals, namely Crystal B, were known in art.

### 8. Patents $\Rightarrow$ 226.6

Process terms in product-by-process claims serve as limitations in determining

patent infringement; overruling *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565..

### 9. Patents $\Rightarrow$ 8

If inventor invents product whose structure is either not fully known or too complex to analyze, inventor is free to use process steps to define product, subject to ordinary requirements of patentability.

### 10. Patents $\Rightarrow$ 101(3)

Phrase "obtainable by," as used in patent for antibiotic crystalline cefdinir, introduced limiting process steps, where patentee's claims did not furnish any test by which to identify cefdinir crystals except that they were result of claimed process, and patentee chose to differentiate prior art reference on basis that its claimed processes were different.

### 11. Patents $\Rightarrow$ 230, 237

Infringement analysis under doctrine of equivalents proceeds element-by-element; generalized showing of equivalency between claim as a whole and allegedly infringing product or process is not sufficient to show infringement.

### 12. Patents $\Rightarrow$ 230, 237

Although primary test for equivalency under doctrine of equivalents is "function-way-result" or "triple identity" test, whereby patentee may show equivalent when accused product or process performs substantially same function, in substantially same way, to achieve substantially same result, as disclosed in claim, equivalency may also be proven where differences between invention as claimed and accused product or process are insubstantial.

### 13. Patents $\Rightarrow$ 251

Owner of patent for antibiotic crystalline cefdinir could not extend its exclusive right in patent's claims under doctrine of equivalents to embrace known but un-

claimed subject matter, even if accused product was bioequivalent to patentee's product, where patentee emphasized sole teaching of Crystal A in communications with Patent and Trademark Office (PTO), as well as in patent specification itself, and removed Crystal B disclosure from parent application, and bulk of accused product was Crystal B, not Crystal A.

#### 14. Patents ⇨237

"Equivalency" for purposes of patent infringement requires element-by-element comparison of patent claim and accused product, requiring not only equivalent function but also equivalent way and result.

See publication Words and Phrases for other judicial constructions and definitions.

#### 15. Patents ⇨251

Bioequivalency of accused product with product produced from patent at issue is not sufficient to establish infringement by equivalents.

#### 16. Federal Courts ⇨815

Court of Appeals reviews grant or denial of preliminary injunction for abuse of discretion.

#### 17. Patents ⇨294

District court may enter preliminary injunction in patent infringement case based on its consideration of four factors: (1) likelihood of patentee's success on merits; (2) irreparable harm if injunction is not granted; (3) balance of hardships between parties; and (4) public interest.

#### 18. Patents ⇨298

District court did not abuse its discretion in denying preliminary injunction in action alleging that generic cefdinir monohydrate products infringed patents for crystalline cefdinir, where patent excluded Crystal B compounds, including cefdinir monohydrate, and there was no evidence that any trace amounts of claimed cefdinir

anhydrate in accused products could be contributing factor in their efficacy.

#### Patents ⇨328(2)

4,559,334. Cited as Prior Art.

#### Patents ⇨328(2)

4,935,507. Construed and Ruled Not Infringed by.

#### Patents ⇨328(4)

4,321. Cited.

James F. Hurst, Winston & Strawn LLP, of Chicago, IL, argued for all plaintiffs-appellants in 2007-1400 and defendants/counterclaimants-appellants in 2007-1446. With him on the briefs for Abbott Laboratories were Todd J. Ehlman, Kathleen B. Barry, and Ivan M. Poullaos, and Steffen N. Johnson, of Washington, DC. Of counsel on the brief for Abbott Laboratories were William F. Cavanaugh, Jr., Jeffrey I.D. Lewis, and Stuart E. Pollack, Patterson Belknap Webb & Tyler LLP, of New York, NY. Of counsel was John C. Knapp. On the briefs for Astellas Pharma, Inc., were Richard D. Kelly, Stephen G. Baxter and Frank J. West, Oblon, Spivak, McClelland, Maier & Neustadt, P.C., of Alexandria, VA.

Meredith Martin Addy, Brinks, Hofer, Gilson & Lionie, of Chicago, IL, argued for defendant-appellee Sandoz, Inc. With her on the brief were Thomas J. Filarski, Mark H. Remus, C. Noel Kaman, and Laura A. Lydigsen. Of counsel was Rashad L. Morgan.

Thomas J. Meloró, Jr., Wilkie Farr & Gallagher LLP, of New York, NY, argued for defendants-appellees Teva Pharmaceuticals USA, Inc., et al. With him on the brief was Neal K. Feivelson. Of counsel were Michael W. Johnson and Alexander H. Swirnoff.

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on the briefs for Abbott  
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son, of Washington, DC. Of  
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K. Feivelson. Of counsel  
J. Johnson and Alexander

Deanne M. Mazzochi, Rakoczy Molino  
Mazzochi Siwik, LLP, of Chicago, IL, ar-  
gued for plaintiff/counterclaim defendant-  
appellee Lupin Limited and counterclaim  
defendant-appellee, Lupin Pharmaceuti-  
cals, Inc. in 2007-1446. With her on the  
brief were William A. Rakoczy, Paul J.  
Molino, and Amy D. Brody.

Before RADER, PLAGER, and  
BRYSON, Circuit Judges. MICHEL,  
Chief Judge, and RADER, BRYSON,  
GAJARSA, LINN, DYK, PROST, and  
MOORE, Circuit Judges, have joined  
Section III.A.2 of the opinion. Dissenting  
opinion as to Section III.A.2 filed by  
NEWMAN, Circuit Judge, in which  
MAYER and LOURIE, Circuit Judges,  
join. Dissenting opinion filed by  
LOURIE, Circuit Judge. SCHALL,  
Circuit Judge, did not participate as a  
member of the en banc court.

RADER, Circuit Judge.

In this case, the same patent, U.S. Pat-  
ent No. 4,935,507 (the '507 patent), occa-  
sions litigation in both the United States  
District Court for the Eastern District of  
Virginia and the United States District  
Court for the Northern District of Illinois.  
The Virginia District Court granted the  
motion of Lupin Ltd. and Lupin Pharma-  
ceuticals Inc. (collectively Lupin) for sum-  
mary judgment of noninfringement. In  
the other case, the Illinois District Court  
denied a preliminary injunction to Abbott  
Laboratories, the exclusive licensee of the  
'507 patent, based on the claim construc-  
tion from the Eastern District of Virginia.

Because the Eastern District of Virginia  
correctly construed the claims of the '507  
patent and correctly discerned no genuine  
issues of material fact on literal infringe-  
ment of claims 2-5 or infringement by  
equivalents of claims 1-5, this court af-  
firms its partial summary judgment of  
noninfringement. Likewise, this court af-  
firms the Northern District of Illinois' de-

nial of Abbott's motion for a preliminary  
injunction, based in large part on the same  
correct claim construction.

I.

Abbott Laboratories, the exclusive licen-  
see of the '507 patent, markets crystalline  
cefdinir according to the '507 patent under  
the trade name Omnicef. The Virginia  
case arose when Lupin sought a declarato-  
ry judgment of noninfringement against  
Abbott Laboratories and Astellas Pharma  
Inc., the owner of the '507 patent (collec-  
tively Abbott). The Food and Drug Ad-  
ministration had previously approved Lu-  
pin's Abbreviated New Drug Application  
(ANDA) to market a generic version of  
Omnicef. Lupin's generic product con-  
tains almost exclusively the Crystal B form  
of crystalline cefdinir (cefdinir monohydr-  
ate), whereas Abbott's Omnicef product  
contains the Crystal A form of crystalline  
cefdinir (cefdinir anhydrate). Further,  
Lupin makes its products with processes  
other than those claimed in the '507 pat-  
ent. For these reasons, Lupin brought  
the Virginia action to clarify that its pro-  
posed product would not infringe a valid  
patent. Abbott counterclaimed for in-  
fringement. The Eastern District of Vir-  
ginia construed the claims, *Lupin Ltd. v.*  
*Abbott Laboratories*, 484 F.Supp.2d 448  
(E.D.Va.2007) (*Lupin CC Order*), and ulti-  
mately granted-in-part Lupin's motion for  
summary judgment of noninfringement, as  
to both literal and equivalent infringement  
for claims 2-5 and as to equivalent in-  
fringement for claim 1, *Lupin Ltd. v. Ab-*  
*bott Labs.*, 491 F.Supp.2d 563 (E.D.Va.  
2007) (*Lupin SJ Order*). The parties stip-  
ulated to the dismissal without prejudice of  
the remaining claims (invalidity) and coun-  
terclaims (literal infringement of claim 1).

In the Illinois action, Abbott sued San-  
doz, Inc. and Sandoz GmbH (collectively  
Sandoz), Teva Pharmaceuticals USA, Inc.

and Teva Pharmaceuticals Industries, Ltd. (collectively Teva), Ranbaxy Laboratories, Ltd., Ranbaxy, Inc., Par Pharmaceutical Companies, Inc., and Par Pharmaceutical (all defendants, collectively, Sandoz and Teva) for infringement of the '507 patent. Like Lupin, Sandoz and Teva had previously filed ANDAs, seeking to market generic versions of Omnicef. Abbott sought a preliminary injunction in the Illinois case. For purposes of that motion, the parties agreed to adopt the Eastern District of Virginia's claim construction from the *Lupin* case. *Abbott Labs. v. Sandoz, Inc.*, 486 F.Supp.2d 767 (N.D.Ill.2007) (*Sandoz PI Order*). Despite this agreement, the parties to the *Sandoz* case disagreed as to how to interpret some of the Eastern District of Virginia's constructions, necessitating some clarification by the Northern District of Illinois. 486 F.Supp.2d at 770-71 (disputing "Crystal A," "peaks," and "about," and seeking construction of "powder X-ray diffraction pattern," which the Eastern District of Virginia had not defined). Ultimately, the Northern District of Illinois, based on the claim construction from Virginia, denied the preliminary injunction.

Both cases arrived at this court on appeal. This court heard the cases together and decides them together with this decision.

## II.

The '507 patent has five claims, all of which Abbott asserts against Lupin as well as Sandoz and Teva. Claim 1 claims crystalline cefdinir, using its chemical name, and defining its unique characteristics with powder X-ray diffraction (PXRD) angle peaks:

1. Crystalline 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) which shows the peaks at the diffraction angles shown in the following

table in its powder X-ray diffraction pattern:

diffraction angle (°)
about 14.7°
about 17.8°
about 21.5°
about 22.0°
about 23.4°
about 24.5°
about 28.1°

'507 patent, col.16 ll.13-27. In contrast, claims 2-5 claim crystalline cefdinir, without any PXRD peak limitations, but with descriptions of processes used to obtain the crystalline cefdinir. Claims 2 and 5 are independent:

2. Crystalline 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) which is obtainable by acidifying a solution containing 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) at room temperature or under warming.

5. Crystalline 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) which is obtainable by dissolving 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) in an alcohol, continuing to stir the solution slowly under warming, then cooling the solution to room temperature and allowing the solution to stand.

*Id.* at col. 16 ll.29-34, 43-50.

These claims use PXRD as a way to claim the structure and characteristics of the unique crystalline form. PXRD is a method for identifying and distinguishing different crystalline compounds. The method beams X-rays toward a powdered chemical. The method then measures the ways the rays reflect or bend upon contact with the chemical. The diffraction angles

under X-ray diffraction pat-

fraction angle (°)

- about  $14.7^\circ$
- about  $17.8^\circ$
- about  $21.5^\circ$
- about  $22.0^\circ$
- about  $23.4^\circ$
- about  $24.5^\circ$
- about  $28.1^\circ$

.16 ll.13-27. In contrast, crystalline cefdinir, with peak limitations, but with processes used to obtain cefdinir. Claims 2 and 5

7-[2-(2-aminothiazol-4-  
minoacetamido)-3-vinyl-  
arboxylic acid (syn iso-  
obtainable by acidifying a  
aining 7-[2-(2-aminothia-  
droxyiminoacetamido)-3-  
m-4-carboxylic acid (syn  
m temperature or under

7-[2-((2-aminothiazol-4-  
iminoacetamido)-3-vinyl-  
carboxylic acid (syn iso-  
obtainable by dissolving  
thiazol-4-yl)-2-hydroxy-  
ol)-3-vinyl-3-cephem-4-  
l (syn isomer) in an alco-  
to stir the solution slowly  
g, then cooling the solution  
temperature and allowing the  
nd.

1—34, 43–50.

use PXRD as a way to measure the purity and characteristics of crystalline form. PXRD is a useful tool for identifying and distinguishing crystalline compounds. The X-rays toward a powdered sample then measures the reflect or bend upon contact with a detector. The diffraction angles

and intensities vary with the type and purity of the test compound. A graph then plots the diffraction angle on one axis and the intensity on another. These graphs yield a unique "fingerprint" for each crystalline form of a chemical. A more sensitive form of X-ray diffraction is single crystal X-ray diffraction (SCXRD). As this name suggests, this method uses only a single crystal as a sample. SCXRD does not detect intensity, but produces a more precise diffraction angle measurement.

The '507 patent was not the first cefdinir patent. Rather, Astellas' prior art U.S. Patent No. 4,559,334 (the '334 patent) describes the discovery of cefdinir as a compound demonstrating high antimicrobial activity. '334 patent, col. 11 ll.18-24. The '334 patent expired on May 6, 2007.

The '507 patent claims priority to Japanese Patent Application No. 62-206199 (the JP '199 application), which claimed two crystalline forms of cefdinir, "Crystal A" and "Crystal B." The JP '199 application claimed Crystals A and B very specifically, defining Crystal A by three infrared (IR)-absorption wavelengths and sixteen PXRD angles and intensities. In contrast, Crystal B featured five IR-absorption wavelengths and twenty-one PXRD angles/intensities.

Despite using the JP '199 application for priority, the '507 patent's specification differs significantly. Specifically, Abbott (actually Fujisawa Pharmaceutical Co., Ltd., Astellas' predecessor in interest) jettisoned the Crystal B disclosure found in the JP '199 application and crafted broader claims in its prosecution of the '507 patent. Because the JP '199 applications defines Crystal A and Crystal B physiochemically rather than structurally, the forms actually represent subgenres of crystalline cefdinir. Thus Crystals A and B comprise crystalline forms of varying structures,

which in the context of this case means varying levels of hydration.

The Eastern District of Virginia construed the claim terms “crystalline,” “shows,” “peaks,” and “about” as follows:

1) "crystalline" means "Crystal A as outlined in the specification";

2) "shows" requires the display of a powder X-ray diffraction pattern which demonstrates the existence of the relevant peaks to a scientifically acceptable degree of certainty either visually or by other appropriate means of data display;

3) "peaks" is the plural of "peak;" a "peak exists at a powder X-ray diffraction angle that corresponds to an intensity measurement greater than measurements attributable to "noise" if that angle is immediately preceded by and followed by powder X-ray diffraction angle with a lower intensity measurement; "noise" refers to those portions of a PXRD pattern produced by intrinsic measurement error, and which cannot be associated with a scientifically significant quantity of the material which is the subject of the PXRD test;

4) "about" encompasses measurement errors inherently associated with powder X-ray diffraction testing.

*Lupin CC Order*, 484 F.Supp.2d at 459, 466. The Eastern District of Virginia also concluded that claims 2-5 were product-by-process claims. *Id.* Later the district court concluded that the process terms of claims 2-5, indicated by the phrase “obtainable by,” limit the claims to the specified processes and process steps. In reaching that conclusion, the trial court followed this court’s opinion in *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed.Cir.1992). *Lupin SJ Order*, 491 F.Supp.2d at 567-68; *Lupin Ltd. v. Abbott Labs.*, No. 3:06-CV-400 (E.D.Va. May 10, 2007) (*Lupin PbyP Order*). In the *Lupin* appeal, Abbott challenges only

the Eastern District of Virginia's constructions of "crystalline" and "obtainable by."

### III.

Evaluation of a summary judgment of noninfringement requires two steps: claim construction, which this court reviews without deference, *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448, 1451 (Fed.Cir.1998) (en banc), and comparison of the properly construed claims to the accused product, process, or composition of matter, which in the context of summary judgment also occurs without deference, see *Ormco Corp. v. Align Technology, Inc.*, 498 F.3d 1307, 1312 (Fed.Cir.2007). Although infringement by equivalency is a question of fact, this court may affirm summary judgment "where no reasonable fact finder could find equivalence." *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1423 (Fed.Cir.1997) (citing *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 39 n. 8, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997)).

#### A. Claim Construction

[1] Because the claims define the patent right, see *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1115 (Fed.Cir.2004), naturally "the claims themselves provide substantial guidance as to the meaning of particular claim terms." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed.Cir.2005) (en banc). But the claims "must be read in view of the specification, of which they are a part." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed.Cir.1995) (en banc), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). A patent's specification provides necessary context for understanding the claims, and "is always highly relevant to the claim construction analysis." *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conception, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996)). While equally true in a general sense, sometimes

the specification offers practically incontrovertible directions about claim meaning. For example, inventors may act as their own lexicographers and give a specialized definition of claim terms. See *id.* at 1316. Likewise, inventors and applicants may intentionally disclaim, or disavow, subject matter that would otherwise fall within the scope of the claim. See *id.*

[2-5] When consulting the specification to clarify the meaning of claim terms, courts must take care not to import limitations into the claims from the specification. This court has recognized the "fine line between" the encouraged and the prohibited use of the specification. *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed.Cir.1998). When the specification describes a single embodiment to enable the invention, this court will not limit broader claim language to that single application "unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed.Cir.2004) (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed.Cir.2002)). By the same token, the claims cannot "enlarge what is patented beyond what the inventor has described as the invention." *Biogen, Inc. v. Berlex Labs., Inc.*, 318 F.3d 1132, 1140 (Fed.Cir.2003) (quoting *Netword, LLC v. Centraal Corp.*, 242 F.3d 1347, 1352 (Fed.Cir.2001)). Thus this court may reach a narrower construction, limited to the embodiment(s) disclosed in the specification, when the claims themselves, the specification, or the prosecution history clearly indicate that the invention encompasses no more than that confined structure or method. See *Liebel-Flarsheim*, 358 F.3d at 908.

[6] Along with the specification, the prosecution history is "intrinsic evidence"

rs practically incontro-  
about claim meaning.  
tors may act as their  
and give a specialized  
rms. See *id.* at 1316.  
and applicants may in-  
or disavow, subject  
herwise fall within the  
See *id.*

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ecification. *Comark  
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v. Medrad, Inc.*, 358  
ir.2004) (quoting *Tele-  
I. Am. Corp.*, 299 F.3d  
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ing *Netword, LLC v.*  
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rsheim, 358 F.3d at

the specification, the  
is "intrinsic evidence"

of the meaning of the claims, because it  
"provides evidence of how the [United  
States Patent & Trademark Office (PTO)]  
and the inventor understood the patent."  
*Phillips*, 415 F.3d at 1317. Although often  
producing ambiguities occasioned by ongo-  
ing negotiations between the inventor and  
the PTO, "the prosecution history can of-  
ten inform the meaning of the claim lan-  
guage by demonstrating how the inventor  
understood the invention and whether the  
inventor limited the invention in the course  
of prosecution, making the claim scope  
narrower than it would otherwise be." *Id.*  
"[C]lear and unmistakable" statements  
during prosecution may also disavow claim  
scope. *Computer Docking Station Corp.*  
*v. Dell, Inc.*, 519 F.3d 1366, 1374 (Fed.Cir.  
2008) (quoting *Purdue Pharma L.P. v.*  
*Endo Pharms., Inc.*, 438 F.3d 1123, 1136  
(Fed.Cir.2006)). Again owing in part to  
the inherent ambiguities of prosecution  
history, the doctrine of prosecution dis-  
claimer only applies to unambiguous disa-  
vowals. See *id.* at 1375.

#### 1. "crystalline"

The Eastern District of Virginia's con-  
struction of "crystalline" in claims 1-5 as  
"Crystal A" included the important caveat  
"as outlined in the specification." *Lupin  
CC Order*, 484 F.Supp.2d at 459. Al-  
though the Eastern District noted the par-  
ties agreed that "crystalline" ordinarily  
means exhibiting "uniformly arranged mol-  
ecules or atoms," *id.* at 454, the court  
relied on the language of the claims them-  
selves, the specification, and the prosecu-  
tion history to arrive at the more specific  
meaning recited in the specification.

[7] The '507 specification states that  
"Crystal A of the compound (I) [cefdinir]  
shows its distinguishing peaks" at the sev-  
en particular PXRD angles enumerated in  
claim 1. '507 patent col.1 ll.51-62. Indeed,  
the phrase "Crystal A of the compound  
(I)" appears throughout the written de-

scription, and the patent offers the follow-  
ing definition: "any crystal of the com-  
pound (I) which shows substantially the  
same diffraction pattern [as in the table in  
col.1/claim 1] is identified as Crystal A of  
the compound (I)." *Id.* at col.1 l.67-col.2  
l.2. As the Eastern District correctly con-  
cluded:

Had Astellas intended, in the chart  
found in column 1, to distinguish Crystal  
A from other forms of crystalline cefdi-  
nir that also fall within the scope of  
claim 1, it would have listed, at a mini-  
mum, an eighth peak associated only  
with Crystal A. However, by listing in  
column 1 only the same seven 'disting-  
uishing' peaks featured in Claim 1, As-  
tellas confirmed that Crystal A was syn-  
onymous with the invention listed in  
Claim 1.

*Lupin CC Order*, 484 F.Supp.2d at 456-57.  
The problem, within the confines of claim  
1, is that defining "crystalline" as "Crystal  
A," where "Crystal A" incorporates the  
seven PXRD peak limitations, arguably  
renders the remainder of that claim redun-  
dant. To distinguish the invention, howev-  
er, the specification refers several times to  
"Crystal A of the compound (I) of the  
present invention," see, e.g., '507 patent,  
col.2 ll.15-17, and offers no suggestion that  
the recited processes could produce non-  
Crystal A compounds, even though other  
types of cefdinir crystals, namely Crystal  
B, were known in the art. As noted earli-  
er, the Crystal B formulation actually ap-  
pears in the parent JP '199 application.  
Thus, Abbott knew exactly how to describe  
and claim Crystal B compounds. Knowing  
of Crystal B, however, Abbott chose to  
claim only the A form in the '507 patent.  
Thus, the trial court properly limited the  
term "crystalline" to "Crystal A." The trial  
court's definition correctly identifies claim  
1's literal scope.



Unlike claim 1, claims 2-5 do not recite the seven PXRD peaks expressly associated with Crystal A in the '507 specification. Nonetheless, the Eastern District of Virginia limited "crystalline" to "Crystal A" in these claims as well. The trial court gave two reasons for this limitation. First, "[t]he process steps detailed in those claims [claims 2-5] correspond with the processes for making Crystal A disclosed in the specification under the heading 'The Process For Preparing Crystal A of The Compound (I).'" *Id.* at 457 (quoting '507 patent, col.2 ll.13-14). Second, the parent JP '199 application recited these steps "to distinguish between preparations of Crystal A and Crystal B." *Id.* (citing JP '199 application, col.6 ll.1-25).

In limiting "crystalline" to "Crystal A" in claims 1-5, the Eastern District of Virginia did not improperly import the preferred embodiment into the claims. Initially, Crystal A is the only embodiment described in the specification. As discussed above, the specification's recitation of Crystal A as its sole embodiment does not alone justify the trial court's limitation of claim scope to that single disclosed embodiment. See *Liebel-Flarsheim*, 358 F.3d at 906 ("[T]his court has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment."). In this case, however, the rest of the intrinsic evidence, including the prosecution history and the priority JP '199 application, evince a clear intention to limit the '507 patent to Crystal A as defined by the seven PXRD peaks in the specification and in claim 1.

Initially, the Eastern District of Virginia properly considered the JP '199 application as relevant objective evidence of the inventor's knowledge at the filing of the '507 patent. While statements made during prosecution of a foreign counterpart to a U.S. patent application have a narrow

application to U.S. claim construction, *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1290 (Fed.Cir.2006), in this case the JP '199 application is part of the prosecution history of the '507 patent itself. Indeed the '507 patent claims priority from the JP '199 application. Furthermore, the trial court did not rely on attorney argument or amendments during a foreign prosecution as in *Pfizer*, but consulted only the contents of the foreign priority application. The JP '199 application strongly suggests that the '507 patent intentionally excluded Crystal B compounds. As discussed above, the JP '199 application establishes unequivocally that Abbott knew and could describe both Crystal A and Crystal B. Abbott could have retained the disclosure of Crystal B to support the broader claims of the '507 patent, but instead disclosed and claimed A alone.

Furthermore, the prosecution history of the '507 patent shows a clear and intentional disavowal of claim scope beyond Crystal A. Co-inventor Takao Takaya, who prepared samples according to Examples 14 and 16 of the prior art '334 patent and a sample of "Crystal A of the present application," offered a declaration that Crystal A was more stable than the prior art samples from the '334 patent. An analytical chemist, Yoshihiko Okamoto, corroborated this evidence. J.A. 501-04. Beyond these declarations, the applicant specifically limited the invention to Crystal A: "the *method of preparation* of the crystalline form of the presently claimed compounds is not considered the heart of the present invention. The crystalline form of the compound represents the inventive concept hereof, and it is clear that [the '334 patent] does not anticipate or suggest said crystalline form." J.A. 511 (Response to Office Action of May 11, 1989, received October 27, 1989, at 6).

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claim construction, *Way Labs. Ltd.*, 457 Cir.2006), in this case a is part of the prosecution history of the '507 patent itself. The claims priority application. Further, did not rely on amendments during a in *Pfizer*, but contents of the foreign The JP '199 application that the '507 patent 1 Crystal B compared above, the JP '199 unequivocally that could describe both al B. Abbott could closure of Crystal B r claims of the '507 closed and claimed

prosecution history of a clear and intended claim scope beyond Takao Takaya, who according to Examples of '334 patent and a of the present application that Crystal n the prior art same. An analytical amato, corroborated l-04. Beyond these ant specifically lim-crystal A: "the meth-crystalline form of compounds is not f the present inven-form of the com-inventive concept at [the '334 patent] suggest said crystal-Response to Office 9, received October

Given the exclusive focus on Crystal A in the specification as well as the prosecution history of the '507 patent, the Eastern District of Virginia properly limited "crystalline" in claims 1-5 to "Crystal A."

## 2. proper interpretation of product-by process claims<sup>1</sup>

This court addresses Part III.A.2 of this opinion en banc, which addresses the proper interpretation of product-by-process claims in determining infringement.

Claims 2-5 of the '507 patent begin by reciting a product, crystalline cefdinir, and then recite a series of steps by which this product is "obtainable." The Eastern District of Virginia correctly categorized claims 2-5 as product-by-process claims. On appeal, Abbott argues that the Eastern District erred in construing the process steps of claims 2-5 under the rule in *Atlantic Thermoplastics*, 970 F.2d at 846-47, that "process terms in product-by-process claims serve as limitations in determining infringement," rather than in accordance with *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1583 (Fed.Cir.1991) ("[T]he correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims."). This court takes this opportunity to clarify en banc the scope of product-by-process claims by adopting the rule in *Atlantic Thermoplastics*.

In *Atlantic Thermoplastics*, this court considered the scope of product-by-process claim 26 in the patent at issue: "[t]he molded innersole produced by the method of claim 1." 970 F.2d at 836. The patentee urged that competing, indistinguishable innersoles made by a different method none-

theless infringed claim 26. *Id.* at 838. This court rejected the patentee's position. This court in *Atlantic Thermoplastics* construed product-by-process claims as limited by the process. *Id.* at 846-47.

This rule finds extensive support in Supreme Court opinions that have addressed the proper reading of product-by-process claims. See *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 493, 23 L.Ed. 952 (1877) ("The process detailed is thereby made as much a part of the invention as are the materials of which the product is composed."); *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222, 224, 26 L.Ed. 149 (1880) ("[T]o constitute infringement of the patent, both the material of which the dental plate is made . . . and the process of constructing the plate . . . must be employed."); *Merrill v. Yeomans*, 94 U.S. 568, 24 L.Ed. 235 (1877); *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293, 4 S.Ct. 455, 28 L.Ed. 433 (1884) (*BASF*); *The Wood-Paper Patent*, 23 Wall. 566, 90 U.S. 566, 596, 23 L.Ed. 31 (1874); *Plummer v. Sargent*, 120 U.S. 442, 7 S.Ct. 640, 30 L.Ed. 737 (1887); *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 58 S.Ct. 899, 82 L.Ed. 1402 (1938); see also *Atl. Thermoplastics*, 970 F.2d at 839-42 (discussing each of these cases). In these cases, the Supreme Court consistently noted that process terms that define the product in a product-by-process claim serve as enforceable limitations. In addition, the binding case law of this court's predecessor courts, the United States Court of Customs and Patent Appeals (see *In re Hughes*, 496 F.2d 1216, 1219 (CCPA 1974) (acknowledging that "true product claims" are "broader" in scope than product-by-process claims)),

1. This court, *sua sponte*, took en banc Section III.A.2 before issuing a panel opinion. The following judges join this section of the opinion: Chief Judge Michel and Judges Rader, Bryson, Gajarsa, Linn, Dyk, Prost, and

Moore. Judges Newman and Lourie dissent in separate opinions. Judges Mayer and Lourie join in Judge Newman's dissent. Judge Schall did not participate as a member of the en banc court.



and the United States Court of Claims (*see Tri-Wall Containers v. United States*, 187 Ct.Cl. 326, 408 F.2d 748, 751 (1969)), followed the same rule.

This court's sister circuits also followed the general rule that the defining process terms limit product-by-process claims. *See, e.g., Hide-It Leather v. Fiber Prods.*, 226 F. 34, 36 (1st Cir.1915) ("It is also a well-recognized rule that, although a product has definite characteristics by which it may be identified apart from the process, still, if in a claim for the product it is not so described, but is set forth in the terms of the process, nothing can be held to infringe the claim which is not made by the process."); *Paeco, Inc. v. Applied Moldings, Inc.*, 562 F.2d 870, 876 (3d Cir. 1977) ("A patent granted on a product claim describing one process grants no monopoly as to identical products manufactured by a different process."). Indeed, this court itself had articulated that rule: "For this reason, even though *product-by-process claims are limited by and defined by the process*, determination of patentability is based on the product itself." *In re Thorpe*, 777 F.2d 695, 697 (Fed.Cir.1985) (emphasis added).

The Supreme Court has long emphasized the limiting requirement of process steps in product-by-process claims. In *BASF*, the Court considered a patent relating to artificial alizarine. Specifically, the patent claimed "[a]rtificial alizarine, produced from anthracine or its derivatives by either of the methods herein described, or by any other method which will produce a like result." 111 U.S. at 296, 4 S.Ct. 455 (quoting U.S. Patent Reissue No. RE 4,321). In turn, the specification generally described a method for making artificial alizarine involving anthracine or its derivatives. Alizarine had been in use for thousands of years as a red textile dye, traditionally extracted from madder root. Pure alizarine has the chemical formula

$C_{14}H_8O_4$ , but "artificial alizarines" available in the market at the time of the litigation varied from almost completely pure alizarine, to combinations of alizarine and anthrapurpurine, to pure purpurine containing no alizarine whatsoever. *Id.* at 309-10, 4 S.Ct. 455. The defendant's product contained approximately sixty percent anthrapurpurine. Thus both alizarine and artificial alizarines were known in the prior art. The Supreme Court clearly articulated some of the scope and validity problems that arise when process limitations of product-by-process claims are ignored:

[The defendant's product] is claimed by the plaintiff to be the artificial alizarine described in No. 4,321, and to be physically, chemically, and in coloring properties similar to that. But what that is is not defined in No. 4,321, except that it is the product of the process described in No. 4,321. Therefore, unless it is shown that the process of No. 4,321 was followed to produce the defendant's article, or unless it is shown that that article could not be produced by any other process, the defendant's article cannot be identified as the product of the process of No. 4,321. Nothing of the kind is shown.

\* \* \*

If the words of the claim are to be construed to cover all artificial alizarine, whatever its ingredients, produced from anthracine or its derivatives by methods invented since Graebe and Liebermann invented the bromine process, we then have a patent for a product or composition of matter which gives no information as to how it is to be identified. *Every patent for a product or composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing can be held to infringe the*

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*Id.* at 3

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ficial alizarines" available the time of the litigation st completely pure alizations of alizarine and an-pure purpurine contain-hatsoever. *Id.* at 309-10, defendant's product con-tely sixty percent anthra-both alizarine and artifi-e known in the prior art. ourt clearly articulated e and validity problems process limitations of s claims are ignored:

's product] is claimed by be the artificial alizarine o. 4,321, and to be physi-y, and in coloring proper-hat. But what that is is o. 4,321, except that it is the process described in refore, unless it is shown ss of No. 4,321 was fol-e the defendant's article, shown that that article oduced by any other pro-dant's article cannot be e product of the process Nothing of the kind is

of the claim are to be ver all artificial alizarine, gredients, produced from ts derivatives by methods Graebe and Liebermann romine process, we then or a product or composi-which gives no informa-n it is to be identified. or a product or composi-must identify it so that it ized aside from the de-process for making it, or n be held to infringe the

patent which is not made by that pro-cess.

*Id.* at 310, 4 S.Ct. 455 (emphasis added).

After *BASF*, the Supreme Court con-tinued to emphasize the importance of process steps in evaluating the infringe-ment of product-by-process claims. See, e.g., *Plummer*, 120 U.S. at 448, 7 S.Ct. 640 ("[W]hatever likeness that may ap-pear between the product of the process described in the patent and the article made by the defendants, their identity is not established unless it is shown that they are made by the same process."); *Gen. Elec. Co.*, 304 U.S. at 373, 58 S.Ct. 899 ("[A] patentee who does not distin-guish his product from what is old except by reference, express or constructive, to the process by which he produced it, can-not secure a monopoly on the product by whatever means produced." (footnote omitted)).

[8] Thus, based on Supreme Court precedent and the treatment of product-by-process claims throughout the years by the PTO and other binding court decisions, this court now restates that "process terms in product-by-process claims serve as limitations in determining infringe-ment." *Atl. Thermoplastics*, 970 F.2d at 846-47. As noted earlier, this holding fol-lows this court's clear statement in *In re Thorpe* that "product by process claims are limited by and defined by the process." 777 F.2d at 697.

More recently, the Supreme Court has reiterated the broad principle that "[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention." *Warner-Jenkin-son*, 520 U.S. at 19, 117 S.Ct. 1040. Al-though *Warner-Jenkinson* specifically ad-dressed the doctrine of equivalents, this rule applies to claim construction overall. As applied to product-by-process claims, *Warner-Jenkinson* thus reinforces the ba-sic rule that the process terms limit prod-

uct-by-process claims. To the extent that *Scripps Clinic* is inconsistent with this rule, this court hereby expressly overrules *Scripps Clinic*.

The dissenting opinions lament the loss of a "right" that has never existed in prac-tice or precedent—the right to assert a product-by-process claim against a defen-dant who does not practice the express limitations of the claim. This court's en banc decision in no way abridges an inven-tor's right to stake claims in product-by-process terms. Instead this decision merely restates the rule that the defining limitations of a claim—in this case process terms—are also the terms that show in-fringement.

Thus this court does not question at all whether product-by-process claims are le-gitimate as a matter of form. The legiti-macy of this claim form was indeed a relevant issue in the nineteenth century when *Ex parte Painter*, 1891 C.D. 200, 200-01 (Comm'r Pat. 1891), and some later cases were before the Commissioner of Patents. However, this court need not address that settled issue. The issue here is only whether such a claim is infringed by products made by processes other than the one claimed. This court holds that it is not.

The jurisprudence of the Court of Cus-toms and Patent Appeals—a court with virtually no jurisdiction to address in-fringement litigation—can shed little light on the enforcement of the only claim limi-tations that an applicant chooses to define the invention. Indeed, this court's venera-ble predecessor expressed its ambivalence towards the relevant infringement analy-sis:

The policy of the Patent Office in per-mitting product-by-process type claims to define a patentable product, where necessary, has developed with full cogni-zance of the fact that in infringement

suits some courts have construed such claims as covering only a product made by the particular process set forth in the claim and not to the product per se. *In re Bridgeford*, 53 C.C.P.A. 1182, 357 F.2d 679, 683 n. 5 (1966). The reference to "some courts" in this prior citation, as this court notes en banc, includes the United States Supreme Court and every circuit court to consider the question, including this circuit. See also Jon S. Saxe & Julian S. Levitt, *Product-by-Process Claims and Their Current Status in Chemical Patent Office Practice*, 42 J. Pat. Off. Soc'y 528, 530 (1960) ("[P]roduct-by-process claims have met with a most strict interpretation in the courts in infringement proceedings. . . . [T]he courts uniformly hold that only a product produced by the claim-designated process may be held to infringe the claim.") (citing *Gen. Elec. Co.*, 304 U.S. 364, 58 S.Ct. 899, 82 L.Ed. 1402 and *BASF*, 111 U.S. at 310, 4 S.Ct. 455).

[9] Product-by-process claims, especially for those rare situations when products were difficult or impossible to describe, historically presented a concern that the Patent Office might deny all product protection to such claims. See *In re Butler*, 17 C.C.P.A. 810, 813, 37 F.2d 623 (1930) ("Process claims are valuable, and appellant thinks he is entitled to them; but it is submitted that he should not be limited to control of the process when the article which that process produces is new and useful."). In the modern context, however, if an inventor invents a product whose structure is either not fully known or too complex to analyze (the subject of this case—a product defined by sophisticated PXRD technology—suggests that these concerns may no longer in reality exist), this court clarifies that the inventor is absolutely free to use process steps to define this product. The patent will issue subject to the ordinary requirements of patentability. The inventor will not be denied protection. Because the inventor

chose to claim the product in terms of its process, however, that definition also governs the enforcement of the bounds of the patent right. This court cannot simply ignore as verbiage the only definition supplied by the inventor.

This court's rule regarding the proper treatment of product-by-process claims in infringement litigation carries its own simple logic. Assume a hypothetical chemical compound defined by process terms. The inventor declines to state any structures or characteristics of this compound. The inventor of this compound obtains a product-by-process claim: "Compound X, obtained by process Y." Enforcing this claim without reference to its defining terms would mean that an alleged infringer who produces compound X by process Z is still liable for infringement. But how would the courts ascertain that the alleged infringer's compound is really the same as the patented compound? After all, the patent holder has just informed the public and claimed the new product solely in terms of a single process. Furthermore, what analytical tools can confirm that the alleged infringer's compound is in fact infringing, other than a comparison of the claimed and accused infringing processes? If the basis of infringement is not the similarity of process, it can only be similarity of structure or characteristics, which the inventor has not disclosed. Why also would the courts deny others the right to freely practice process Z that may produce a better product in a better way?

In sum, it is both unnecessary and logically unsound to create a rule that the process limitations of a product-by-process claim should not be enforced in some exceptional instance when the structure of the claimed product is unknown and the product can be defined only by reference to a process by which it can be made. Such a rule would expand the protection of

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the patent beyond the subject matter that  
the inventor has "particularly point[ed] out  
and distinctly claim[ed]" as his invention,  
35 U.S.C. § 112 ¶ 6.

Thus, the Eastern District of Virginia  
correctly applied the rule that the recited  
process steps limit the product-by-process  
claims 2-5 for any infringement analysis.

### 3. "obtainable by"

[10] In this case, Abbott's plain lan-  
guage argument, that "obtainable by" in-  
troduces an optional process, even if  
"obtained by" would introduce limiting  
process steps, is also unavailing. The  
BASF case, an analogous situation to  
this case, controls. As noted above, the  
Supreme Court in BASF considered the  
following claim language: "Artificial al-  
izarine, produced from anthracine or its  
derivatives by either of the methods  
herein described, or by any other meth-  
od which will produce a like result."  
111 U.S. at 296, 4 S.Ct. 455 (emphasis  
added). The patentee argued that even  
though the defendant did not make arti-  
ficial alizarine by "either of the methods  
herein described," the claim should cap-  
ture the product because of the "or by  
another method" language. *Id.* at 309, 4  
S.Ct. 455. The Supreme Court refused  
to attach importance to those expansive  
words: "No. 4,321 furnishes no test by  
which to identify the product it covers,  
except that such product is to be the  
result of the process it describes." *Id.*  
at 305, 4 S.Ct. 455. Abbott's claims 2-  
5, like those in BASF and like product-  
by-process claims in general, do not fur-  
nish any test by which to identify the  
cefdinir crystals except that they are the  
result of their respectively claimed pro-  
cesses. As per BASF, Abbott's claim  
cannot capture a product obtained by or  
obtainable by processes other than those  
explicitly recited in the claims.

If this court were to strip the process  
elements from the claims, as Abbott would  
urge, for infringement purposes, there  
would then be nothing to differentiate in-  
dependent claim 2 from independent claim  
5. After all, if those claims are not bound  
by the process terms but only "define" the  
basic cefdinir compound, then each of the  
claims recite the same thing, over and over  
again. Though Abbott argues that it  
merely intends to give meaning to the  
word "obtainable," it instead seeks to have  
this court render meaningless the explicit  
process limitations that the applicant chose  
to define its invention.

The intrinsic evidence in this case fur-  
ther rebuts Abbott's contention that its  
claims are not limited to those products  
actually obtained by the processes recited.  
In column 2 of the '507 patent, under the  
title heading "The Process for Preparing  
Crystal A of the Compound (I)," the paten-  
tee used specific language to describe the  
very two processes that are mirrored in  
claims 2 and 5. '507 patent col.2 ll.13-51.  
This language is not open-ended, nor does  
it constitute a mere description of the  
product by reference to the manner in  
which it can be made, as Abbott argues.  
By drafting claims 2 and 5 to incorporate  
these specific processes, Abbott made a  
conscious choice to place process require-  
ments on its claimed product. If Abbott  
had wanted to obtain broader coverage for  
crystalline cefdinir devoid of any process  
limitations, as it seeks to do here, it could  
have simply done so (if indeed, as it ar-  
gues, it is really the product that is the  
heart of the invention, not the process).  
But it did not. The crystals of claims 2  
and 5 are simply not identifiable other  
than by the processes disclosed in column  
2. This court must enforce the ways and  
terms that a party chooses to define its  
invention.

The prosecution history also does not support Abbott's contention that "obtainable by" offers merely an optional set of definitional process conditions. During prosecution, Abbott faced obviousness rejections based on application claims 6-9, which were process claims that mirrored the *very* process limitations of issued claims 2-5. The PTO refused to issue the claims until one set of duplicates was cancelled. Abbott's action in cancelling claims 6-9 demonstrates its acquiescence to the PTO's view that the process elements of claims 2-5 are critical parts of those claims. In addition, in a response to the PTO's office action, Abbott chose to differentiate a cited § 103 reference, Takaya, on the basis that Abbott's claimed processes are different. For these reasons, the applicant's statement in the file wrapper that "the method of preparation . . . is not considered the heart of the present invention" should not be afforded undue gravitas. The process limitations cannot be haphazardly jettisoned for an infringement analysis when they were so important in the patentability analysis.

In sum, a patentee's use of the word "obtainable" rather than "obtained by" cannot give it a free pass to escape the ambit of the product-by-process claiming doctrine. Claims that include such ambiguous language should be viewed extremely narrowly. If this court does not require, as a precondition for infringement, that an accused infringer actually use a recited process, simply because of the patentee's choice of the probabilistic suffix "able," the very recitation of that process becomes redundant. This would widen the scope of the patentee's claims beyond that which is actually invented—a windfall to the inventor at the expense of future innovation and proper notice to the public of the scope of the claimed invention. For all the above reasons, the Eastern District of Virginia correctly construed the process limitations beginning with "obtainable by" in claims

2-5 as limiting the asserted claims to products made by those process steps.

### B. Summary Judgment

In the *Lupin* case, the Eastern District of Virginia granted summary judgment of noninfringement of claims 2-5, both literal and by equivalents, and of claim 1 by equivalents. *Lupin SJ Order*. Literal infringement of claim 1, i.e., whether Lupin's generic cefdinir product contains any Crystal A, is therefore not a live issue on appeal. As for claims 2-5, the Eastern District noted that "Abbott and Astellas have conceded that literal infringement of Claims 2-5 cannot be established if the product-by-process analysis is performed pursuant to *Atlantic Thermoplastics*," given that "Abbott and Astellas have presented no evidence that Lupin is practicing the process steps set forth in Claims 2-5." *Lupin SJ Order*, 491 F.Supp.2d at 568. Because the Eastern District correctly applied the rule from *Atlantic Thermoplastics* and likewise properly construed the limiting process terms in claims 2-5, only infringement by equivalents of claims 1-5 remains before this court.

[11, 12] Infringement analysis under the doctrine of equivalents proceeds element-by-element; a generalized showing of equivalency between the claim as a whole and the allegedly infringing product or process is not sufficient to show infringement. See *Warner-Jenkinson*, 520 U.S. at 29, 117 S.Ct. 1040 ("the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole"). The primary test for equivalency is the "function-way-result" or "triple identity" test, whereby the patentee may show an equivalent when the accused product or process performs substantially the same function, in substantially the same way, to achieve substantially the same result, as disclosed in the claim.

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*Graver Tank & Mfg. Co. v. Linde Air  
Prods. Co.*, 339 U.S. 605, 608, 70 S.Ct. 854,  
94 L.Ed. 1097 (1950). But, because "[d]if-  
ferent linguistic frameworks may be more  
suitable to different cases," *Warner-Jen-*  
*kinson*, 520 U.S. at 40, 117 S.Ct. 1040, the  
function-way-result test is not the only test  
for equivalency. Equivalency may also be  
proven where the differences between the  
invention as claimed and the accused prod-  
uct or process are insubstantial. *Hilton  
Davis Chem. Co. v. Warner-Jenkinson  
Co.*, 62 F.3d 1512, 1517-18 (Fed.Cir.1995)  
(en banc), *rev'd on other grounds*, 520 U.S.  
17, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997).  
In no case, however, may the doctrine of  
equivalents ignore the individual claim ele-  
ments. See *Warner-Jenkinson*, 520 U.S.  
at 40, 117 S.Ct. 1040 (requiring "a special  
vigilance against allowing the concept of  
equivalence to eliminate completely any  
such [individual] elements").

Because "crystalline" in claims 1-5 is  
limited to "Crystal A" as defined by the  
seven PXRD peaks enumerated in claim 1  
and in the specification of the '507 patent,  
the doctrine of equivalents cannot capture  
crystals that are not themselves equivalent  
to Crystal A. In turn, the bounds of Crys-  
tal A equivalents cannot ignore the limits  
on Crystal A in the '507 patent, which as  
discussed above, includes a conscious deci-  
sion to distinguish Crystal B from the  
claimed invention. To recall, the applicant  
removed Crystal B from the U.S. prosecu-  
tion of the parent JP '199 application.  
The '507 patent indisputably describes and  
claims Crystal A, and not Crystal B. The  
'507 patent, of course, could have claimed  
the known Crystal B formulation which  
was known to the inventors because it  
appeared in their priority JP '199 applica-  
tion. The applicants chose not to claim  
Crystal B. Thus Crystal B compounds,  
most relevantly cefdinir monohydrate, fall  
outside the scope, literal or equivalent, of  
claims 1-5 of the '507 patent.

[13] The parties agree that the "bulk"  
of Lupin's cefdinir product is Crystal B,  
not Crystal A. The degree to which Lu-  
pin's product may or may not also contain  
Crystal A is the central inquiry regarding  
the alleged literal infringement of claim 1,  
which is not part of the present appeal.  
Abbott cannot extend its exclusive right in  
the '507 claims under the doctrine of  
equivalents to embrace known but un-  
claimed subject matter. In other words,  
Abbott effectively disclaimed Crystal B  
during prosecution of the '507 patent, by  
removing the Crystal B disclosure from  
the parent JP '199 application and empha-  
sizing the sole teaching of Crystal A in  
communications with the PTO as well as in  
the '507 specification itself. Abbott cannot  
now recapture that unclaimed subject mat-  
ter under the doctrine of equivalents be-  
cause the Eastern District properly inter-  
preted claims 2-5 to limit "crystalline" to  
Crystal A. To expand that claim term to  
embrace Crystal B would ignore the spe-  
cific claim limitations of the '507 patent.

Alternatively this court notes that this  
case seems to fit within the dedication  
doctrine that forecloses invocation of the  
doctrine of equivalents. The patent appli-  
cant clearly knew of the Crystal B forms  
of the claimed invention because it claimed  
and disclosed them in its Japanese priority  
application. Yet it declined to claim an  
embodiment expressly disclosed in its pri-  
ority document, thus dedicating that em-  
bodiment to the public and foreclosing any  
recapture under the doctrine of equiva-  
lents. See *Johnson & Johnston Assocs. v.  
R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed.  
Cir.2002).

During prosecution, Abbott chose to es-  
chew Crystal B and focus exclusively on  
Crystal A compounds. Without a com-  
plete record and no arguments about valid-  
ity before this court on appeal, this court  
cannot speculate on the reasons for this

choice. Nonetheless, the parties hotly contest whether Example 14, which reports obtaining "crystals" not specifically identified or described, and/or Example 16 of the '334 patent enable cefdinir monohydrate, i.e. Crystal B type crystals.

[14, 15] Beyond the attempt to reinflate the claims to encompass Crystal B based on mathematical comparisons of the PXRD peak patterns of Crystal A and Crystal B, Abbott also asserts that Lupin effectively admitted infringement by equivalents when it claimed before the Food and Drug Administration that its cefdinir generic was a bioequivalent to Abbott's Omnicef product. While bioequivalency may be relevant to the function prong of the function-way-result test, bioequivalency and equivalent infringement are different inquiries. Bioequivalency is a regulatory and medical concern aimed at establishing that two compounds are effectively the same for pharmaceutical purposes. In contrast, equivalency for purposes of patent infringement requires an element-by-element comparison of the patent claim and the accused product, requiring not only equivalent function but also equivalent way and result. Different attributes of a given product may thus be relevant to bioequivalency but not equivalent infringement, and vice versa. As the Northern District of Illinois observed in the *Sandoz* case, "[i]f bioequivalency meant per se infringement, no alternative to a patented medicine could ever be offered to the public during the life of a patent." *Sandoz PI Order*, 486 F.Supp.2d at 776. Thus, while potentially relevant, the bioequivalency of an accused product with a product produced from the patent at issue is not sufficient to establish infringement by equivalents.

Because Crystal B is not an equivalent of Crystal A, the Eastern District of Virginia did not err in granting summary judgment of noninfringement of claims 2-5,

both with respect to literal and equivalent infringement, and with respect to equivalent infringement of claim 1.

#### IV.

[16, 17] This court reviews the grant or denial of a preliminary injunction for abuse of discretion. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed.Cir.2001). A district court may enter a preliminary injunction based on its consideration of four factors: "(1) the likelihood of the patentee's success on the merits; (2) irreparable harm if the injunction is not granted; (3) the balance of hardships between the parties; and (4) the public interest." *Erico Int'l Corp. v. Vutec Corp.*, 516 F.3d 1350, 1353-54 (Fed.Cir.2008) (quoting *PHG Techs., LLC v. St. John Cos., Inc.*, 469 F.3d 1361, 1365 (Fed.Cir.2006)).

Sandoz and Teva's Omnicef generic products, like Lupin's, are also at least primarily cefdinir monohydrate, a Crystal B compound. *Sandoz PI Order*, 486 F.Supp.2d at 769. Before the Northern District of Illinois, the parties to the *Sandoz* litigation disputed whether Sandoz and Teva's products also contained small amounts of cefdinir anhydrate, i.e., Crystal A, which would fall within the literal scope of claim 1 of the '507 patent. Working primarily from the Eastern District of Virginia's claim construction, to which the parties to the *Sandoz* litigation agreed would bind their litigation as well for purposes of the preliminary injunction motion, the Northern District of Illinois denied Abbott's motion for a preliminary injunction, finding that Abbott was unlikely to prevail on the merits at trial.

[18] This court detects no abuse of discretion in the Northern District of Illinois' preliminary injunction denial. As described above, the '507 patent is properly construed to exclude Crystal B, both as to

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literal and equivalent infringement. Thus,  
this court need not delve into the Northern  
District of Illinois' clarifications of the  
Eastern District of Virginia's claim con-  
structions. The Northern District of Illi-  
nois succinctly concluded: "[w]e know that  
Crystal B was known to the plaintiffs be-  
cause it had been included in the Japanese  
'199 patent. Thus we conclude that the  
plaintiffs deliberately excluded from the  
definition of Crystal A, cefdinir monohy-  
drate, which is Crystal B." *Id.* at 775.

As to the alleged presence of small  
amounts of Crystal A in Sandoz and Teva's  
products, Abbott's evidence did not per-  
suade the Northern District of Illinois.  
*Id.* This court perceives that decision as  
well within the trial court's discretion. As  
additional support, the Northern District  
observed that there was no evidence that  
any trace amounts of cefdinir anhydrate,  
i.e. Crystal A, in Sandoz and Teva's prod-  
ucts "could be a contributing factor in the  
efficacy" and that even "if there is a small  
amount of cefdinir anhydrate in defen-  
dants' products, we do not conclude that  
this could cause literal infringement." *Id.*  
While these may be misstatements of the  
law, because *de minimis* infringement can  
still be infringement, *see* 35 U.S.C.  
§ 271(a); *see also SunTiger, Inc. v. Sci.*  
*Res. Funding Group*, 189 F.3d 1327, 1336  
(Fed.Cir.1999) ("If a claim reads merely on  
a part of an accused device, that is enough  
for infringement."), this court need not  
reach that issue in a preliminary injunction  
context which affords the trial court broad  
leeway to discern a "likelihood of success."  
Likewise the district court may have over-  
stated the relevance of efficacy, because  
the '507 patent contains no claim limita-  
tions relating to efficacy. But these mis-  
statements were harmless because they  
merely formed an alternative basis for the  
Northern District of Illinois' reasonable  
assessment of the evidence proffered by  
Abbott for its preliminary injunction mo-  
tion. As noted, this court sustains the

trial court's discretion based primarily on  
its administration of the proper claim con-  
struction and its finding that Abbott was  
not likely to show Sandoz and Teva's prod-  
ucts contained any Crystal A at all.

## CONCLUSION

The Eastern District of Virginia correct-  
ly construed the '507 patent's recitation of  
"crystalline" in each of the asserted claims  
as limited to Crystal A, as outlined in the  
specification. Because Abbott scrubbed all  
references to Crystal B in the '507 patent's  
specification, which were present in the  
'507 patent's parent foreign application,  
Abbott clearly demonstrated its intent to  
limit the '507 patent to Crystal A. This  
intent was further underscored by com-  
ments made during prosecution. As such,  
Abbott is unable to recapture Crystal B  
through broad claim language or under the  
doctrine of equivalents. The Eastern Dis-  
trict of Virginia therefore properly con-  
cluded on summary judgment that Lupin's  
cefdinir product did not infringe claims 1-5  
literally or claims 2-5 by equivalency.  
Similarly, the Northern District of Illinois  
did not abuse its discretion in declining to  
enter a preliminary injunction against San-  
doz and Teva's cefdinir products.

## AFFIRMED

## COSTS

Each party shall bear its own costs.

NEWMAN, Circuit Judge, with whom  
Circuit Judges MAYER and LOURIE  
join, dissenting from en banc Section  
III.A.2.

The court today acts *en banc* to overturn  
a century of precedent and practice, and  
holds that a new product that is difficult to  
describe without reference to how it was  
made, but that is nonetheless a new and  
unobvious product, cannot be protected as

a product if its description is aided by reference to how it was made. Heretofore a new product whose structure was not fully known or not readily described could be patented as a product by including in the product description sufficient reference to how it can be made, to distinguish the new product from prior art products. Patentability was determined as a product, independent of any process reference in the claim, and validity and infringement were based on the product itself. This expedient for patenting products whose structure was not fully known at the time of filing the patent application has been called the "rule of necessity." It was pragmatic, fair, and just, for it attuned patent law and practice to the realities of invention.

Today the court rejects this expedient and discards this practice, ruling that all claims containing a process term under the rule of necessity now must be construed, for purposes of infringement, as limited to use of any process term that was used to assist in defining the product. That is, such a product is not patented as a product, however it is produced, but is limited to the process by which it was obtained. This is a new restraint on patents for new products, particularly today's complex chemical and biological products whose structure may be difficult to analyze with precision. It is a change of law with unknown consequences for patent-based innovation.

The court acts *sua sponte*, without explanation of what policy is intended to be served by this change, without consideration of the technologies that may be adversely affected by elimination of this expedient, without notice to those whose

property rights may be diminished. In so doing, the court departs from statute, precedent, and practice. This change is as unnecessary as it is flawed, gratuitously affecting inventions past, present, and future. I respectfully dissent.

#### DISCUSSION

For most product inventions, the process by which the product was made, whether or not the process is itself a patentable invention, is not stated in the product claims. However, as the variety and complexity of invention and technology have increased, various forms of product claims with process terms have been used in specific circumstances, depending on the nature of the invention.<sup>1</sup> The form here at issue relates to product claims for new and unobvious products whose structure is not fully known, and for which process parameters are used to aid in defining the product. This claiming expedient has been recognized since at least 1891.

The court today overturns this expedient for all circumstances, brooking no exception. Acting *en banc* for the purpose, the court rules that if any process term or descriptive aspect is included in a product claim to aid in distinguishing a new product, the claim cannot be infringed by the identical product unless the same process aspect is used in making the accused product. The court holds that it is irrelevant whether the product is new or was known, irrelevant whether the product could have been fully described by its structure at the time of the patent application, irrelevant whether the particular invention is a new product or is actually a process. The court adopts a simplistic universal rule,

claims, product claims with a process limitation, product claims with a process-derived structural element, and product claims with functional terms.

1. As discussed by Eric P. Mirabel, *Product-By-Process Claims: A Practical Perspective*, 68 J. Pat. & Trademark Off. Soc'y 3, 3-4 (1986), the various forms of product-by-process claims include "true" product-by-process

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## DISCUSSION

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class of inventions. The effect of this deci-  
sion on innovation in complex fields of  
science and technology is unknown to the  
court, for we have had no advice on the  
consequences of this change of law. My  
dissent is directed as much to the court's  
procedure, as to the substance of the  
court's decision.

## I

### PROCEDURE

The court has given no notice of this  
impending *en banc* action, contrary to the  
Federal Rules of Appellate Procedure and  
contrary to the Federal Circuit's own oper-  
ating procedures. The *en banc* court has  
received no briefing and held no argument,  
although the Federal Rules so require.  
The communities of inventors, innovators,  
and the public who may be affected by this  
change of law have had no opportunity to  
be heard. The court has received no infor-  
mation concerning the effect on patents  
that were granted based on this long-es-  
tablished practice, no advice on what kinds  
of inventions may now lie fallow because  
they are unprotected. Nor does the court  
explain its suspension of the standards of  
judicial process.

The Federal Rules have the force of  
law. 28 U.S.C. § 2072. Federal Rules of  
Appellate Procedure 34 and 35 are here  
implicated. Rule 34 provides that "oral  
argument must be allowed in every case"  
unless certain specific exceptions exist:

**Rule 34(a)(2) Standards.** Oral argu-  
ment must be allowed in every case  
unless a panel of three judges who have  
examined the briefs and record unani-  
mously agrees that oral argument is un-  
necessary for any of the following rea-  
sons:

- (A) the appeal is frivolous;
- (B) the dispositive issue or issues  
have been authoritatively decided; or

(C) the facts and legal arguments are  
adequately presented in the briefs and  
record, and the decisional process  
would not be significantly aided by  
oral argument.

Applying the Rule 34 standards, it is clear  
that (A) this appeal is not frivolous and (B)  
the dispositive issue has not been authori-  
tatively decided, for it is currently being  
addressed *en banc*. There has been (C) no  
briefing and no record to the court, and  
this is not a case in which the decisional  
process would not be aided by oral argu-  
ment. The *en banc* court has heard no  
argument, and has received neither writ-  
ten nor oral exploration of the diverse  
aspects of this long-established claiming  
practice.

Federal Rule of Appellate Procedure 35  
has also failed of compliance. That rule  
recognizes the exceptional nature of *en  
banc* hearing or rehearing, and identifies  
the two circumstances warranting such  
procedure:

**Rule 35(a)**... An *en banc* hearing or  
rehearing is not favored and ordinarily  
will not be ordered unless:

- (1) *en banc* consideration is necessary  
to secure or maintain uniformity of  
the court's decisions; or
- (2) the proceeding involves a question  
of exceptional importance.

When an *en banc* hearing or rehearing is  
ordered *sua sponte* by the court, whether  
for uniformity of decision or on a question  
of exceptional importance, the hearing or  
rehearing must receive the appellate pro-  
cess set by the Rules.

I agree that *en banc* review is appropri-  
ate, for this apparent conflict in our prece-  
dent has existed since 1992. Now that the  
court has undertaken to resolve the con-  
flict, the withholding of public notice, or  
even notice to the parties to this case, is  
devoid of justification. The question is of  
importance, but there has been no asser-

tion of urgency sufficient to require bypassing the standard appellate procedures. The breadth of the *en banc* court's ruling, the solidity of the precedent now overruled, the importance of the technologies affected, and the untold issued patents that are now placed in limbo, require this court's compliance with Federal Rules 34 and 35.

The Federal Circuit has recognized that it can benefit from the advice of those knowledgeable in the law and its purposes, in the areas of our nation-wide responsibility. Patent law has a direct impact on innovation, industry, and technological advance, and when an *en banc* ruling may change the law affecting some areas of technology and the industries based thereon, this court has routinely sought to be informed, by the parties and *amici curiae*, of relevant concerns. When the impact of a *sua sponte* change of law transcends the interests of the parties to the specific case, notice to the interested public, as well as to the parties, is fundamental to due and fair process. The Federal Circuit's Internal Operating Procedure (IOP) 14 was adopted to implement these principles:

IOP 14.3(c) If the *sua sponte* petition for hearing *en banc* is granted, a committee of judges appointed by the chief judge, which shall normally include the judge who initiated the poll, shall within seven working days (fourteen working days between June 21 and September 11) transmit on a vote sheet to the judges who will sit *en banc* an order setting forth the questions proposed to be addressed by the court *en banc*. The clerk shall provide notice that a majority of the judges in regular service has acted under 28 U.S.C. § 46 and Fed. R.App. P. 35(a) to order the appeal to be heard *en banc*, and indicate any questions the court may wish the parties and *amici* to address. Notice shall be given that the court *en banc* shall consist of all circuit judges in regular service who are not

recused or disqualified. Additional briefing and oral argument will be ordered as appropriate.

*United States Court of Appeals for the Federal Circuit, Internal Operating Procedures* at 40, available at <http://www.cafe.uscourts.gov/pdf/IOPs122006.pdf>. This IOP has not been followed. No notice was given, even to the parties, that the court had ordered this question to be reheard *en banc*; nor did the court advise the parties or the public as to the aspects being addressed for *en banc* decision. The court is acting *sua sponte*, without notice and without argument and without an opportunity for participation. By bypassing this court's standard operating procedure, as well as violating the Federal Rules of Appellate Procedure, the court has deprived itself of input concerning the experience of precedent, of advice as to how this change of law may affect future innovation, and of guidance as to the effect on existing property rights.

## II

### PRECEDENT AND PRACTICE

The court's opinion does not mention the long-established precedent that it is overturning. This is not a simple conflict between isolated rulings of the Federal Circuit; it is a change of law and practice with roots in century-old decisions. I start with this precedent, for the expedient of what came to be called the "rule of necessity" originated in the recognition, by the courts and the Patent Office, that not all new products could be fully described by their structure, due to the state of scientific knowledge or available analytical techniques. It was also recognized, over a century ago, that sufficient distinction from prior art products could sometimes be achieved by reference to how the product was made. Thus the courts and patent administrators established the exception

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*of Appeals for the Federal Circuit* at <http://www.cafc.Us122006.pdf>. This IOP ved. No notice was parties, that the court sition to be reheard en urt advise the parties the aspects being ad-decision. The court is ithout notice and with-ithout an opportunity

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## II

### AND PRACTICE

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that permitted inclusion in a product claim of sufficient recitation of how the product was made, to aid in identifying the product and distinguishing it from the prior art. This claim form was loosely called a "product-by-process" form, although that term includes a variety of situations, *see n. 1 supra*, having diverse legal consequences. The only form here at issue is that in which the product is new and its structure is not fully or readily known, such that its definition as a product is aided by referring to how it was made. Since before 1891, this has been an accepted way to claim products as products, recognizing that this is an exception to the general rule that new products are claimed without reference to the process by which they are produced.

This exception was discussed in 1891 in *Ex parte Painter*, the Commissioner of Patents explaining that when there is entitlement to a patent on a new article of manufacture, it can be claimed by reference to the process of producing it, when the inventor lacks other language to "define and discriminate" the invention:

It requires no argument to establish the proposition that *as a rule* a claim for an article of manufacture should not be defined by the process of producing that article. On the other hand, when a man has made an invention his right to a patent for it, or his right to a claim properly defining it, is not to be determined by the limitations of the English language. When the case arises that an article of manufacture is a new thing, a useful thing, and embodies invention, and that article cannot be properly defined and discriminated from prior art otherwise than by reference to the process of producing it, a case is presented which constitutes an exception to the rule.

1891 C.D. 200, 200-01 (Comm'r Pat. 1891). The Commissioner cited, as an earlier ex-

ample of this exception, the claim in *Globe Nail Co. v. U.S. Horse Nail Co.*, 19 F. 819 (C.C.D.Mass.1884) (sustaining validity of claim directed to horse-shoe nail claimed by reference to its process of manufacture, and finding it infringed by the accused nail having only a "trivial and unsubstantial variation" from the claimed product). In contrast, where the patent application made clear that the product could be described by its structure, the Patent Office ruled that the exception did not apply. *See, e.g., Ex parte Scheckner*, 1903 C.D. 315, 315-16 (Comm'r Pat.1903) (sustaining rejection of claim directed to an etched printing-plate that "specifies certain steps by means of which the etching is accomplished" because other claims "define the plate in terms of its structure").

This expedient has been discussed in various judicial decisions. In all cases the issue has not been whether this expedient was available, for its availability was not challenged; the issue was simply its application to the particular facts. For example, at a time when it heard direct appeals from Patent Office rulings, the D.C. Circuit remarked on this "only exception" to the general rule of product claiming, stating:

It is a well-settled rule of patent law that claims for a product which is defined by the process of producing it will not be allowed; and the only exception to this rule seems to be in cases where the product involves invention and *cannot be defined except by the process used in its creation*. In extreme cases of this character, the product may be allowed; but that is not this case, especially in view of the broad claims allowed appellant in his copending application. . . .

*In re Brown*, 29 F.2d 873, 874 (D.C.Cir. 1928) (emphasis added).

The Court of Customs and Patent Appeals discussed precedent involving claims



for processes and products in various factual situations, and summarized that:

Where it is possible to define a product by its characteristics, the practice is clearly settled that this should be done. Where, however, the product is novel and involves invention and *cannot be defined except by the steps of the process involved in its creation*, there are cases holding that such a claim may be allowed, and it has been sustained by a Court.

*In re Butler*, 17 C.C.P.A. 810, 37 F.2d 623, 626 (1930) (emphasis added) (quoting *Ex Parte Feisenmeier*, 1922 C.D. 18 (Comm'r Pat.1922)). The CCPA then found this rule inapplicable to the facts of *Butler's* invention, explaining that "the record at bar does not meet this requirement [that the product was new]." *Id.*

In *In re Lifton*, 38 C.C.P.A. 1119, 189 F.2d 261 (1951), the CCPA again commented on this exception for product claims, stating that when "proper article claims" were possible they must be used, with the exception of when such claims are "impossible":

This court has uniformly held that a claim for an article must define the article by its structure and not by the process of making it. The one exception to this rule, where the invention is the article and *it is impossible to otherwise define it*, is clearly ruled out in the present case because appellant has demonstrated the possibility of proper article claims by including several devoid of process limitations.

*Id.* at 263 (emphasis added, citations omitted). The court again recognized "the one exception," holding once again that it does not apply when the product can be described independently of the process of making it.

These inquiries into the facts warranting application of the exception demonstrate that the rule of necessity was seldom ap-

plied, but was nonetheless recognized both by the courts and the Patent Office. Decisions of the Patent Office Board of Appeals illustrate the practice. See, e.g., *Ex parte Pfennig*, 65 U.S.P.Q. 577 (Pat.Off. Bd.App.1945) (allowing claim "directed to a product which results from the method of claim 9" in light of applicant's argument that "it is impossible in the instant case to define the product adequately in terms of the elements which compose it or in terms of its physical characteristics"); *Ex parte Lessig*, 57 U.S.P.Q. 129 (Pat.Off.Bd.App. 1943) (allowing claim for a "product containing vulcanized rubber" strongly adhered to fibers which "has been prepared by the process of claim 4" because "it is not possible to otherwise distinguish over the art of record").

Commentators have explained that this claiming practice became of increasing importance as the complex sciences blossomed. See, e.g., Mark D. Passler, *Product-by-Process Patent Claims: Majority of the Court of Appeals for the Federal Circuit Forgets Purpose of the Patent Act*, 49 U. Miami L.Rev. 233, 233 n. 3 (1994) ("Such claims are often used by companies to patent complex drug or chemical products whose structure is not completely understood and, therefore, can only be accurately described by the process through which it is made."). It is well known that the full structure of some chemical and biological products is not always known at the time the patent application is filed. Indeed, it is a tenet of the scientific method that explanation and theory tend to follow, not precede, the observation of a development in the science.

The CCPA continued to recognize the use of process terms to aid in describing new products—the form of claim sometimes called a "pure" product-by-process claim, see n. 1 *supra*—and repeatedly ruled that such claims are properly viewed

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My colleagues misstate the holding of *Bridgeford*, for *Bridgeford* directly contravenes today's holding. In *Bridgeford* the CCPA noted that "some courts" have construed claims with process steps as limited to the recited process, *id.* at 683 n. 5, apparently without inquiring whether the

rulings among the circuits. See *Commission on Revision of the Federal Court Appellate System Structure and Internal Procedures: Recommendations for Change*, 67 F.R.D. 195, 370 (1975).



claims"). The need for this expedient, and the proper scope afforded such claims, is summarized in the treatise *Walker on Patents*:

[P]atent rights over a chemical product are typically independent of the process by which the product is made, and are particularly valuable because of this fact. This independence is normally accomplished by defining the product in terms of its structural features alone, with no reference in the claims to process steps whatsoever. *The state of chemical technology, however, is sometimes too limited for a structural description of this type to be made.* The structure of some chemicals, especially those including elaborate polymer chains, cannot be accurately determined. The same chemicals, however, may be both economically valuable and technologically reproducible, in the sense that they can be reliably made by subjecting a particular set of raw materials to a particular set of process steps.

\* \* \*

The law reacted to these difficulties by making it easier to obtain traditional product protection over this special class of chemicals. The inventor was allowed to describe such a chemical in terms of how one gained possession of it, that is, by way of the process steps by which it was made. Once he did so, the law preserved to the inventor the fullest measure of product-only protection that it could; *it treated the process recitations as proxies for the direct recitations of structure that could not be made.* Such a claim was therefore equivalent to one stated in terms of structure only. It would broadly dominate all methods by which the chemical could be made or used. At the same time, it carried the same dangers of running afoul of the art: it would be anticipated if the chemical had been pro-

duced previously, even if by a method other than what the inventor disclosed.

1 *Moy's Walker on Patents* § 4:74 (4th ed.2008) (emphases added).

The *en banc* court appears to misunderstand this precedent, for my colleagues now state that "binding case law" of the Court of Customs and Patent Appeals and the Court of Claims mandates a single rule for all claims that contain any process terms, whether the product is novel or known, citing *In re Hughes*, 496 F.2d 1216 (CCPA 1974), for this proposition. However, *Hughes* does not state this proposition; *Hughes* stands for the contrary proposition. In *Hughes* the question was the patentability of claims directed to "shakes" as are used in roofing, as follows:

12. Shakes manufactured from a shake bolt by the process of making a plurality of cuts into and across the shake bolt to an extent to establish predetermined tip lengths, and splitting the weather end portions of the shakes from the bolt by starting the splits at the inner ends of the cuts and continuing the splits to the end of the bolt.

This claim had been rejected as an improper product-by-process claim, on the ground that the product could be described without including process steps. The *Hughes* court acknowledged the general rule against product-by-process claiming, but also explained the "proper exception to the general rule" as first set forth in *Painter*, as follows:

[T]he Commissioner of Patents enunciated the general rule that a product should not be defined in terms of the process of making it. In *Painter*, a proper exception to the general rule was found on the ground that the product could not be properly defined and discriminated from the prior art otherwise than by reference to the process of producing it. This basic rule and the ex-

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en rejected as an improper process claim, on the ground could be described without process steps. The *Hughes* rejected the general rule of product-by-process claiming, but "proper exception to the first set forth in *Painter*,

owner of Patents enunciates a rule that a product defined in terms of the thing it. In *Painter*, a departure to the general rule was around that the product properly defined and distinguished from the prior art otherwise related to the process of production basic rule and the ex-

ception have been recognized and followed continuously by the Patent Office and the Courts.

*Hughes*, 496 F.2d at 1218 (quoting approvingly the Solicitor's argument). The court reaffirmed that "in spite of the fact that a product-by-process claim may recite only process limitations, 'it is the product which is covered by the claim and not the recited process steps.'" *Id.* Contrary to my colleagues' statement, *Hughes* did not eliminate this form of claim, or change its role as a product claim. Indeed, the *Hughes* court applied the exception and reversed the Board's rejection of a product-by-process claim, stating:

We agree with appellant that the [general] rule should not be applied to the situation before us. We have been shown no true product claim which describes appellant's invention, in the words of the solicitor, "in terms of structure or physical characteristics." When an applicant seeks to describe his invention by a product-by-process claim because he finds that his invention is incapable of description solely by structure or physical characteristics, it is incumbent upon the Patent Office to indicate where, or how, the applicant's invention is, or may be, so described.

*Id.* at 1219. My colleagues could hardly have selected less apt support for their construction of product-by-process claims, for *Hughes* explicitly states that such claims are for the product, not the process.

In addition to misstating precedent of the CCPA, the *en banc* court also mischaracterizes the decisions of our predecessor the Court of Claims, stating that the Court of Claims' decisions support today's ruling. The court cites *Tri-Wall Containers v. United States*, 187 Ct.Cl. 326, 408 F.2d 748 (1969), for this purpose. That citation, too, is mysterious, for in *Tri-Wall Containers* the court found that the claimed product was not "new" because it had been on sale

for more than the permitted period, although the product that was on sale had been made by a different process than the process stated in the claim. The Court of Claims stated that the evidence showed that "the prior art product and the claimed product are structurally identical," *id.* at 751, and explained that a known product cannot be patented by including process terms in the claim:

It is well established that a product claimed as made by a new process is not patentable unless the product itself is new. *The Wood-Paper Patent*, 90 U.S. (23 Wall.) 566, 596, 23 L.Ed. 31 (1874), *Cochrane v. Badische Anilin & Soda Fabrik* ["BASF"], 111 U.S. 293, 311, 4 S.Ct. 455, 28 L.Ed. 433 (1884)....

More recent cases point out that the addition of a method step in a product claim, which product is not patentably distinguishable from the prior art, cannot impart patentability to the old product. *Jungersen v. Baden*, 69 F.Supp. 922, 928 (S.D.N.Y.1947), *aff'd*, 166 F.2d 807 (2d Cir.1948), *aff'd*, 335 U.S. 560, 69 S.Ct. 269, 93 L.Ed. 235 (1949); *In re Stephens*, 345 F.2d 1020, 1023, 52 C.C.P.A. 1409 (1965).

*Tri-Wall Containers*, 408 F.2d at 750-51. This case applied the standard rule that old products cannot be patented—it contains no statement limiting the scope of claims that include process aspects to aid in describing new products. The Supreme Court cases cited in *Tri-Wall* are all directed to new processes for making old products—these are the same cases that the *en banc* court today incorrectly applies to new products, as I discuss *post*.

Contrary to my colleagues' statement, CCPA and Court of Claims precedent do not support today's *en banc* thesis. Our predecessor courts understood the complexity of patenting, and the CCPA consis-

tently implemented the expedient whereby process terms contributed to the description of complex new products of incompletely known structure. These courts recognized the independence of product claims for new products, and did not limit such claims to the specific process steps that were used to aid in describing the product.<sup>3</sup>

With the advent of the Federal Circuit, this court continued to apply these principles. In *In re Thorpe*, 777 F.2d 695 (Fed. Cir.1985), the court explained that product-by-process claims are anticipated when the product existed in the prior art, even if the product was made by a different process. My colleagues are mistaken in stating that *Thorpe* held that all such claims are to be construed as process claims, even when the product is new and the rule of necessity justifies this mode of describing the invention. In *Thorpe* the product was not new; it was a known color developer for carbonless paper copy systems, and this court held that the PTO correctly rejected the claim to "the product of the process of claim 1," explaining that since the product was old it could not be claimed as a product, whether or not process steps are recited in the claim.

The facts of *Thorpe* did not concern the exception and expedient where process terms are invoked to describe a new product of complex structure. This exception

3. The *en banc* court impugns the CCPA's experience. Maj. op. at 1293 (stating that the CCPA had "virtually no jurisdiction to address infringement litigation"). The CCPA for many years addressed infringement litigation, in appeals from the International Trade Commission and its predecessor tribunals. E.g., *Sealed Air Corp. v. Int'l Trade Comm'n*, 68 C.C.P.A. 93, 645 F.2d 976 (1981) (issues of validity and infringement); *Hale Fire Pump Co. v. Tokai, Ltd.*, 67 C.C.P.A. 121, 614 F.2d 1278 (1980) (issues of validity, scope, and infringement); *In re Orion*, 22 C.C.P.A. 149, 71 F.2d 458 (1934) (issues of jurisdiction and infringement).

is rarely invoked. The general rule requiring claims to have a process-free definition of the structure of a new product accommodates most inventions. Some recent exceptions are seen in emerging aspects of biotechnology. For example, in *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 706 F.Supp. 94 (D.Mass.1989), *aff'd in relevant part*, 927 F.2d 1200 (Fed.Cir. 1991), the district court considered the following claim:

4. A procaryotic or eucaryotic host cell transformed or transfected with a DNA sequence according to claim 1, 2 or 3 in a manner allowing the host cell to express erythropoietin.

*Id.* at 108. The district court found claim 4 "ambiguous," explaining that while it is directed to a new product—this host cell—the words "transformed or transfected" appear to invoke a process. The district court recognized that "[i]n the traditional patent framework, a product is wholly separate and distinct from a process." *Id.* at 107. The court observed that "[a] product patent gives the patentee the right to restrict the use and sale of the product regardless of how and by whom it was manufactured," while "[a] process patentee's power extends only to those products made by the patented process." *Id.* (quoting *United States v. Studiengesellschaft Kohle*, 670 F.2d 1122, 1127-28 (D.C.Cir. 1981)). The district court, affirmed by the

Our predecessor's legal and scholarly distinction in the field of patent law, and the high regard in which Congress and the innovation communities held the jurisprudence of the CCPA were a critical foundation for formation of the Federal Circuit and its charge to reinvigorate the role of the patent system in service to the nation's technological innovation. See 125 Cong. Rec. 23,462 (1979) (statement of Sen. DeConcini) ("It is a reflection of high esteem which Congress has for the sitting judges of the Court of Claims and Court of Customs and Patent Appeals that these judges will become the first judges of the new Court of the Federal Circuit.").

The general rule requires a process-free definition of a new product inventions. Some reason in emerging assembly. For example, in *Genentech v. Sandoz*, 927 F.2d 1200 (Fed. Cir. 1991), the court considered the fol-

lowing: "eucaryotic host cell infected with a DNA to claim 1, 2 or 3 in the host cell to ex-

cept court found claim 1 stating that while it is a product—this host cell—was "infected or transfected" process. The district court "[i]n the traditional product is wholly separate a process." *Id.* at 1207, stating that "[a] product does not have the right to represent the product re-ferred to by the patentee's process patentee's to those products of the process." *Id.* (quoting *Studengesellschaft v. W. L. Gore & Co.*, 1127-28 (D.C. Cir. 1991), affirmed by the

Supreme Court and scholarly dis-sentiment in patent law, and the Supreme Court's ongoing and the innovation of the jurisprudence of the Federal Circuit and its charge of the patent system in technological innovation. Rec. 23,462 (1979) (Mancini) ("It is a reflection of the fact that Congress has for the first time given the Court of Claims and Patent Appeals that the first judges of the Federal Circuit.")

Federal Circuit, found this claim to be valid and infringed as a product claim, and although many issues and arguments were present in this litigation, the applicability of the venerable rule of necessity was not at issue.

In *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991), the Federal Circuit addressed the interpretation and scope of claims exemplified by claim 13:

13. Highly purified and concentrated VIII:C prepared in accordance with the method of claim 1.

Claim 1 set forth the method referred to in claim 13, as follows:

1. An improved method of preparing Factor VIII procoagulant activity protein [VIII:C] comprising the steps of
  - (a) adsorbing a VIII:C/VIII:RP complex from a plasma or commercial concentrate source onto particles bound to a monoclonal antibody specific to VIII:RP,
  - (b) eluting the VIII:C,
  - (c) adsorbing the VIII:C obtained in step (b) in another adsorption to concentrate and further purify same,
  - (d) eluting the adsorbed VIII:C, and
  - (e) recovering highly purified and concentrated VIII:C.

It was not disputed that the product was a new product, that the "highly purified and concentrated" blood clotting Factor VIII:C had not previously been obtained, and that a complete structural identification of Factor VIII:C was not available. The defendant Genentech had made its commercial Factor VIII:C not by the method set forth in claim 1, but by using a sample of the Scripps product to "clone" Factor VIII:C protein using recombinant DNA techniques. One question presented in the case was whether claims such as claim 13 were infringed by the same product produced by a different method, or whether such claims were infringed only if the ac-

cused infringer used the process of claim 1.

Scripps stressed that its product was novel and enabled and was patentable as a product, although the full structure of Factor VIII:C was not available at that stage of the science. The court addressed whether claims exemplified by claim 13, properly construed, were product claims, or whether they were limited to the specific processes in the process claims to which they referred. This court held that the claims were product claims. The court held that since claims are construed the same way for infringement as for validity, the question was whether the Genentech product was the same as the claimed product, not whether they were produced by the same process. The court remanded to the district court for this factual determination. *Scripps*, 927 F.2d at 1584.

After *Scripps* was decided, a panel of this court decided an appeal concerning plastic innersoles for shoes. In *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992), the claims at issue were represented by:

Claim 24. The product produced by the method of claim 1.

In turn, claim 1 was as follows:

1. In a method of manufacturing a shock-absorbing, molded innersole for insertion in footwear, which method comprises:

- (a) introducing an expandable, polyurethane into a mold; and
- (b) recovering from the mold an innersole which comprises a contoured heel and arch section composed of a substantially open-celled polyurethane foam material, the improvement which comprises:

(i) placing an elastomeric insert material into the mold, the insert material having greater shock-absorbing

properties and being less resilient than the molded, open-celled polyurethane foam material, and the insert material having sufficient surface tack to remain in the placed position in the mold on the introduction of the expandable polyurethane material so as to permit the expandable polyurethane material to expand about the insert material without displacement of the insert material; and

(ii) recovering a molded innersole with the insert material having a tacky surface forming a part of the exposed bottom surface of the recovered innersole.

The panel held that a claim in the form of claim 24 always requires use of the referenced method, and that it is irrelevant whether the product was new or known. The court stated that the rule of necessity, as applied in *Scripps*, is contrary to Supreme Court rulings. The panel stated that the decision in *Scripps* is incorrect. A majority of the Federal Circuit declined to resolve the conflict *en banc*, resulting in several further opinions. *E.g.*, *Atlantic Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1279 (Fed.Cir.1992) (dissents of Chief Judge Nies and Judges Rich, Newman, and Lourie from denial of rehearing *en banc*). Judge Rich wrote:

[T]his whole excursion was unnecessary because the patentee admitted that claim 24, the product-by-process claim, was limited to the process. The claim read: "The molded innersole produced by the method of claim 1." There was, therefore, no occasion to review the law to determine how the claim should be construed. . . . We are not here to provide restatements of the law. Such restatements should not be made without an opportunity for all affected parties to be heard from. The affected parties here are not the vendors of inner soles but largely the entire chemical industry,

particularly the pharmaceutical manufacturers.

*Id.* at 1280 (Rich, J., dissenting from denial of rehearing *en banc*).

Most trial courts continued to recognize the rule of necessity. For example, in *Trustees of Columbia University v. Roche Diagnostics GmbH*, 126 F.Supp.2d 16 (D.Mass.2000), the district court considered claims such as the following.

72. A eukaryotic cell into which foreign DNA I has been inserted in accordance with the process of claim 54.

The court referred to the *Scripps/Atlantic* conflict, concluded that the earlier panel decision controlled under the Federal Circuit's rule, *see Newell Companies, Inc. v. Kenney Manufacturing Co.*, 864 F.2d 757, 765 (Fed.Cir.1988) ("This court has adopted the rule that prior decisions of a panel of the court are binding precedent on subsequent panels unless and until overturned *in banc*."), and applied the *Scripps* ruling, holding that the new cell was not limited by the process by which it was made.

The PTO also continued to apply the rule of necessity. In instructing examiners that products should whenever possible be described without reference to how they were made, the PTO continued to point out the exception that patentability as a product is not foreclosed when independent description is not available. The Manual of Patent Examining Procedure (MPEP) instructs the examiner to consider the structure implied by any process steps in the claim:

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to im-

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MPEP § 2113 (8th ed., July 2008 rev.). This has been the practice since at least *Ex parte Painter* in 1891. I am surprised at the *en banc* court's casual misstatement about "the treatment of product-by-process claims throughout the years by the PTO," maj. op. at 1293, for the statement is directly contrary to the treatment of such claims throughout the years by the PTO.

The *en banc* court's insistence that one universal rule should now be applied is contrary to the entire body of decisional law, including the Supreme Court cases cited by my colleagues. As I next discuss, in most of the cited cases the product was not a new product and thus was not patentable as a product, whether or not any process term was included in the claim. The Court consistently held that when the product was old and only the process was a patentable invention, a claim for the "product of that process" could not cover the old product made by a different process. That is, and has always been, the law. I comment briefly on the Court's cases that my colleagues misinterpret and misapply:

***Cochrane v. BASF***

The *en banc* opinion relies primarily on *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293, 4 S.Ct. 455, 28 L.Ed. 433 (1884) ("*BASF*"), even though my colleagues acknowledge that the product in that case was the well-known dye alizarine. The patent before the Court was a reissue patent that claimed artificial alizarine in the following way:

Artificial alizarine, produced by either of the methods herein described, or by any other method which will produce a like result.

The Court held that since alizarine was a known product, the claim was limited to the patentee's two processes, stating:

It was an old article. While a new process for producing it was patentable, the product itself could not be patented, even though it was a product made artificially for the first time, in contradistinction from being eliminated from the madder root. Calling it artificial alizarine did not make it a new composition of matter, and patentable as such, by reason of its having been prepared, artificially, for the first time, from anthracite, if it was set forth as alizarine, a well-known substance. *Wood-Paper Patent*, 23 Wall. 566, 593 [23 L.Ed. 31 (1874)]. There was therefore no foundation for reissue No. 4,321, for the product, because, on the description given, no patent for the product could have been taken out originally.

111 U.S. at 311–12, 4 S.Ct. 455. The Court accordingly limited the claim to the two processes described in the patent, and in the portion of *BASF* quoted by my colleagues, the Court discussed the proofs needed to show infringement:

[U]nless it is shown that the process of [the specification] was followed to produce the defendants' article, or unless it is shown that the article could not be produced by any other process, the defendants' article cannot be identified as the product of the process of [the specification]. Nothing of the kind is shown.

*Id.* at 310, 4 S.Ct. 455. The Court did not state, or imply, despite my colleagues' contrary theory, that a claim to a new and complex product that is of necessity defined and distinguished by the process by which it was made, can never be infringed unless that specific process is practiced. There was no issue in *BASF* of a product that could not be defined without reference to how it was made. The *BASF* Court, providing guidance, remarked on the importance of independent description of a

patented product, in the following sentence cited by my colleagues:

Every patent for a product or composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process.

*Id.* at 310, 4 S.Ct. 455. This statement is indeed the general rule, as stated by the Patent Commissioner several years later in *Ex parte Painter*. However, *BASF* did not present the situation for which the expedient of necessity was created, for as the Court stated, the invention was "a process for preparing alizarine, not as a new substance prepared for the first time, but as the substance already known as alizarine, to be prepared, however, by the new process, which process is to be the subject of the patent, and is the process of preparing the known product alizarine from anthracine." *Id.* at 308-09, 4 S.Ct. 455.

This was not an instance of a new product describable only in terms of its process of manufacture. The *BASF* decision lends no support to today's *en banc* rule that every product claim that mentions a process step is always restricted to that process, with no exception, no expedient, no preservation of the distinctions among forms of claim based on the nature of the invention.

#### *The Goodyear Dental cases*

The *en banc* court also states that its new ruling is supported by two cases relating to a patent on the use of vulcanized rubber to form a plate for holding dentures, *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. (3 Otto) 486, 23 L.Ed. 952 (1876), and *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. (12 Otto) 222, 26 L.Ed. 149 (1880). Review of these cases reveals no support for the *en banc* court's state-

ment of their holdings. The claim at issue was:

The plate of hard rubber or vulcanite, or its equivalent, for holding artificial teeth, or teeth and gums, substantially as described.

*Davis*, 102 U.S. (12 Otto) at 223. The claim was written in the then-standard format of incorporating the description in the specification through the phrase "substantially as described." This was not a product-by-process or product-of-the-process claim at all, for the claim contains no process distinction or limitation, but simply refers to the description in the specification. Nonetheless, the *en banc* majority appears to state that these cases mean that the Supreme Court requires that all claims for products whose method of production is set forth in the specification—as is required by the description and enablement requirement—cannot be infringed unless that method is used.

That is not what the *Goodyear Dental* cases said. The Court referred to the position of Goodyear Dental Vulcanite that its patent covered all dental plates made of vulcanized rubber, and held, upon reviewing the specification and the prior art, that the process of manufacture was what distinguished this dental plate from the prior art dental plates, and concluded: "The invention, then, is a product or manufacture made in a defined manner. It is not a product alone, separated from the process by which it is created." *Smith*, 93 U.S. (3 Otto) at 493. Were the claim not limited to this process, the Court concluded that the claim would not have been patentable. *See id.* at 492 (holding that if the patent were for a "mere substitution of vulcanite for other materials, which had previously been employed as a base for artificial sets of teeth" then it "constituted no invention"). Four years later, considering the same patent in *Davis*, the Court empha-

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the *Goodyear Dental* ourt referred to the Dental Vulcanite thai dental plates made of d held, upon review- nd the prior art, that acture was what dis- plate from the prior concluded: "The in- duct or manufacture nner. It is not a ed from the process " *Smith*, 93 U.S. (3 he claim not limited ourt concluded that ive been patentable. g that if the patent titution of vulcanite hich had previously se for artificial sets itituted no inven- er, considering the the Court empha-

sized that the claim was limited to use of vulcanized rubber or its equivalent, and held that since the accused infringer made its dental plate with celluloid, there could not be infringement. See 102 U.S. (12 Otto) at 228–30.

The court today cites these cases as definitive of the interpretation of claims with process elements, although the only process referent is the phrase "substantial- ly as described." This flawed reasoning was disposed of in 1890 in the classic *Rob- inson on Patents*, and until now has not reappeared:

In stating Claims certain phrases are frequently employed to which a special importance seems to be attached by ap- plicants. Among these are the phrase "substantially as described" and others of the same meaning. These phrases import the same thing when used in a Claim as when elsewhere employed. They are neither necessary nor techni- cal. The reference they make to the Description is always implied, and re- lates only to the essential features of the invention as therein delineated. They add nothing, therefore, to the certainty of the Claim, nor do they detract from it unless the claimant carelessly inserts them as a substitute for a more clear and definite statement of his invention.

II W.C. Robinson, *Robinson on Patents* 517 (1890) (footnotes omitted).

#### *Merrill v. Yeomans*

My colleagues also rely on *Merrill v. Yeomans*, 94 U.S. (4 Otto) 568, 24 L.Ed. 235 (1877). Again, the relevance is re- mote. The *Merrill* Court explained that the issue was the "correct construction of plaintiff's patent," *id.* at 569, construing the following claim:

[T]he above-described new manufacture of the deodorized heavy hydrocarbon oils, suitable for lubricating and other purposes, free from the characteristic odors of hydrocarbon oils, and having a

slight smell like fatty oil, from hydrocar- bon oils, by treating them substantially as hereinbefore described.

*Id.* at 570. The Court examined the speci- fication to determine what was invented, and found that the invention was directed solely to a process, not to a product. The Court then concluded that the claim's us- age "new manufacture" referred to the manufacturing process, and not to the product. The claim was thus a process claim, and no "product-by-process" issue was presented. The Court concluded that the defendant's oil, which was made by a different process, did not infringe.

The *Merrill* Court discussed its practice of looking to the patent application and interpreting the claim in light of what was "really invented":

[W]here it appears that a valuable in- vention has really been made, this court, giving full effect to all that is found in the application on which the Patent Of- fice acted, will uphold that which was really invented, and which comes within any fair interpretation of the patentee's assertion of claim.

*Id.* at 573. This approach is inimical to the *en banc* court's theory that it is irrele- vant what the patentee describes as his invention, and that if a process step is mentioned in the claim or "substantially described" in the specification, the claim always requires performance of that step. Although the Court in *Merrill* was not confronted with a situation of indescriba- ble product or necessity bred of complex- ity—indeed no product at all was claimed—neither did the Court hold that every product invention must be limited by the process that produced the product.

#### *The Wood Paper Patent case*

The list of Supreme Court cases relied on by my colleagues continues with *The Wood-Paper Patent*, 90 U.S. 566, 596, 23

Wall. 566, 23 L.Ed. 31 (1874), where claims with the standard "substantially as described" language were construed in two reissue patents relating to the pulping of wood to make paper. The Court explained that one reissue patent was for "a product or manufacture, and not for the process by which the product may be obtained," and the other "for a process and not for its product." *Id.* at 593. The Court examined the prior art and concluded that the claim for the product could not be sustained, because the product produced by the inventor's new pulping process was not new:

Paper-pulp obtained from various vegetable substances was in common use before the original patent was granted to Watt & Burgess, and whatever may be said of their process for obtaining it, the product was in no sense new. The reissued patent, No. 1448, is, therefore, void for want of novelty in the manufacture patented.

*Id.* at 596. The Court then discussed the reissue patent for the "process and not for its product," and held this reissue void because it claimed a different invention than in the original patent. The Court also discussed several other patents directed to boilers used to produce paper-pulp, and to a process for bleaching straw. Nothing in this case concerns the product-by-process issue on which the court is today acting.

I cannot discern why the *en banc* court relies on *The Wood-Paper Patent* case as invalidating *Scripps*, and the court has not attempted to explain.

#### ***Plummer v. Sargent***

The *en banc* court also relies on *Plummer v. Sargent*, 120 U.S. 442, 7 S.Ct. 640, 30 L.Ed. 737 (1887), which again provides no support for my colleagues' thesis. This case again illustrates the Court's practice of reviewing what the patentee stated he invented as set forth in the specification in light of the prior art. The claim in *Plum-*

*mer* was for a "new manufacture," "substantially as described":

What I claim and desire to procure by letters patent is the new manufacture hereinabove described, consisting of iron ornamented in imitation of bronze by the application of oil and heat, substantially as described.

*Id.* at 445, 7 S.Ct. 640. The trial court had found non-infringement because the defendant had used a prior art process for bronzing iron. This prior process was work of F.W. Brocksieper, an employee of the defendant's predecessor company. The Supreme Court affirmed, stating that the claims were limited to the process described in the specification:

It seems necessarily to follow from this view either that the Tucker patents are void by reason of anticipation practiced by Brocksieper, or that the patented process and product must be restricted to exactly what is described. . . .

*Id.* at 449, 7 S.Ct. 640. The Court thus limited the claims to the process described by the patentee, not because of any rule about limiting a product to how it was made in the specification, but to sustain validity of the patent in view of the Brocksieper prior art. The decision in *Plummer* is unrelated to any rule of claim construction based on whether process terms are included in the claim.

These nineteenth-century cases do not relate to the *en banc* court's new universal rule of claim construction, whereby all product claims having process terms are treated as process claims, whatever the nature of the product, whatever the need for process descriptors, or any other factor that precedent shows to be relevant to the exception that is here at issue as to the use of and construction of such claims. Nor do any more recent Court cases.

#### ***General Electric v. Wabash***

My colleagues also cite *General Electric Co. v. Wabash Appliance Corp.*, 304 U.S.

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364, 58 S.Ct. 899, 82 L.Ed. 1402 (1938),  
although the relevance of this case is,  
again, not apparent, for it involved no  
product-by-process claims, but rather  
claims that recite the properties of the  
product. A typical claim is claim 25, which  
describes an electric lamp filament com-  
posed of tungsten grains of a size and  
shape that prevents sagging of the fila-  
ment:

25. A filament for electric incandescent  
lamps or other devices, composed sub-  
stantially of tungsten and made up  
mainly of a number of comparatively  
large grains of such size and contour as  
to prevent substantial sagging and off-  
setting during a normal or commercially  
useful life for such a lamp or other  
device.

*Id.* at 368, 58 S.Ct. 899. The Court held  
this claim "invalid on its face" for failing to  
provide a "distinct and definite statement  
of what he claims to be new, and to be his  
invention." *Id.* at 369, 58 S.Ct. 899. The  
Court stated that the description of the  
grains as "of such size and contour as to  
prevent substantial sagging and offsetting"  
was "inadequate as a description of the  
structural characteristics of the grains."  
*Id.* at 370, 58 S.Ct. 899. The Court also  
criticized the use of functional language in  
the claim, stating that such terms were too  
indefinite to provide clear guidance. *Id.* at  
371, 58 S.Ct. 899. There was no issue of  
whether process steps in the claims were  
regarded as limiting, for there were no  
process steps in the claims. Instead, the  
Court stated that even the implicit inclu-  
sion of process steps could not save the  
claim, because the description of the pro-  
cess in the specification was inadequate:

4. It is curious to observe this *en banc* court  
extolling decisions of the regional circuits as  
authoritative, while it disregards the decisions  
of our predecessor courts and of this court.  
This court was created to remove patent law

Even assuming that definiteness may be  
imparted to the product claim by that  
part of the specification which purport-  
edly details only a method of making the  
product, the description of the Pacz pro-  
cess is likewise silent as to the nature of  
the filament product.

*Id.* at 373, 58 S.Ct. 899. The Court held  
the patent invalid for lack of a "distinct  
and definite" description of the invention,  
for the court "doubted whether one who  
discovers or invents a product he knows to  
be new will ever find it impossible to de-  
scribe some aspect of its novelty." *Id.*  
Whatever the inadequacies in the Pacz  
description of his invention, the Court's  
optimistic view of scientific capability can-  
not be deemed to have barred all recourse  
to the rule of necessity when it is warrant-  
ed, or to have voided the ensuing seventy-  
one years of Patent Office and judicial  
recognition of this pragmatic expedient.

No Supreme Court case discussed the  
problems of complexity and structural  
analysis that warrant this expedient, or  
created a legal solution to these problems.  
It is inappropriate, unsupported by law or  
precedent, and contrary to the purposes of  
patent systems, for this court now to rule  
that such products cannot be patented as  
products.

### Regional circuit decisions

My colleagues also rely on some deci-  
sions of the regional circuits preceding this  
court's formation, announcing that "our  
sister circuits also followed the general  
rule that the defining process terms limit  
product-by-process claims," and citing two  
cases, one decided in 1915 and one in 1977.  
These cases do not support the *en banc*  
court's opinion,<sup>4</sup> and raised no issue of an  
expedient based on necessity.

questions from the regional circuit courts.  
See H.R. Rep. 96-1300, at 20 (1980) ("Direct-  
ing patent appeals to the new court will have  
the beneficial effect of removing these unusu-

In *Hide-It Leather Co. v. Fiber Products Co.*, 226 F. 34 (1st Cir.1915), the appeal was of two process claims for making leatherboard, and a product claim for leatherboard "made from pulp" and reciting the second step in the process claims plus the reference "substantially as described." The accused infringer did not use the same first step of the process. The court found that the invention was for a process, not a product, and therefore that the product claim was not infringed.

My colleagues also cite *Paeco, Inc. v. Applied Moldings, Inc.*, 562 F.2d 870, 876 (3d Cir.1977), in which the court used the specification to resolve an ambiguity in the language of a product claim relating to "replica wooden beams" made of foamed urethane. The court reviewed whether ambiguous claim language required a closed or open mold, for this determined the question of anticipation based on a prior art reference that used an open mold. Thus the court stated that the manufacturing process described in the specification was "of paramount importance," and construed the claim in light of that process as requiring a closed mold, thus preserving the claim's validity as against the prior art that used and open mold. The sentence quoted by my colleagues out of its context, does not relate to the *en banc* court's new rule concerning process terms in product claims, and the *Paeco* case raised no question of whether the product was capable of description apart from the process.

ally complex, technically difficult, and time-consuming cases from the dockets of the regional courts of appeals.... [T]he central purpose is to reduce the widespread lack of uniformity and uncertainty of legal doctrine that exist in the administration of patent law.""); see also *Federal Courts Improvement Act of 1979: Hearings Before the Subcomm. on Improvements in Judicial Machinery of the Comm. on the Judiciary, U.S. Senate*, 96th Cong. 197 (1979) (statement of Hon. Henry J. Friendly) ("What is needed is a group of

In addition to these two cases inaptly cited by the *en banc* court, other regional circuit decisions also contradict this court's new thesis. In *Dunn Wire-Cut Lug Brick Co. v. Toronto Fire Clay Co.*, 259 F. 258 (6th Cir.1919), the court stated: "Certain it is, in view of the weight of authority and the latest decisions, that the inventor of a new and useful product or article of manufacture may have a patent which covers it and gives a monopoly upon it regardless of great variations in the method of making." *Id.* at 261.

In *Buono v. Yankee Maid Dress Corp.*, 77 F.2d 274 (2d Cir.1935) (L.Hand, J.), the court held invalid a product claim for a kind of "blind stitch" used in sewing, because the invention lay only in the process of producing the stitch, which itself "was not new." *Id.* at 279. While the stitch had not been claimed as the product of a particular machine or process, the court remarked on the conceivability of patenting such a product "merely as the product of a machine or process, even though it were anticipated if made in other ways," *id.*, observing that such a claim might serve a useful purpose in protecting against products that were produced by the same machine or process abroad and then imported. Of such a claim, wherein the product itself was anticipated but the process was new, the court stated "it would in that case not be infringed by anything but the product of the ... process." *Id.* This routine statement of estab-

judges, some but not all patent lawyers, with scientific training and interest, aided both by law clerks of similar bent and by a staff of experts in a variety of technologies, such as the Court of Customs and Patent Appeals has had for years and the courts of appeals in the very nature of things, cannot ..."). To cite two regional circuit decisions, while jettisoning the precedents of the court uniquely qualified to address patent questions and selected to supplant the regional circuits, is puzzling.

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Judge H. ple related product its explained t the produc regardless makes it; invention, chine or p was also claims, p forward t Circuit.<sup>5</sup>

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these two cases inaptly *en banc* court, other regional also contradict this court's *Dunn Wire-Cut Lug Brick Fire Clay Co.*, 259 F. 258. The court stated: "Certain the weight of authority and, thus, that the inventor of a product or article of manufacture a patent which covers it solely upon it regardless of in the method of making."

*Kankee Maid Dress Corp.*, Cir.1935) (L.Hand, J.), the court found a product claim for a "stitch" used in sewing, because it lay only in the process of making the stitch, which itself "was made" at 279. While the stitch was claimed as the product of a machine or process, the court considered the conceivability of patenting it "merely as the product of a process, even though it is made in other ways," that such a claim might be proper in protecting the purpose in protecting that were produced by the machine or process abroad and. If such a claim, wherein it was anticipated but the court, the court stated "it must not be infringed by the product of the . . . prior art statement of estab-

lished law does not mean that when the product is itself new and useful and unobvious, it cannot be claimed as a product but must be tied to the machine that made it.

not all patent lawyers, with great skill and interest, aided both by the law and by a staff of experts in the technology of technologies, such as patents and Patent Appeals has the courts of appeals in the past, cannot . . ."). To cite such decisions, while jettisoning of the court uniquely qualified questions and selected regional circuits, is puzzling.

lished law does not mean that when the product is itself new and useful and unobvious, it cannot be claimed as a product but must be tied to the machine that made it.

Judge Hand emphasized that this example related only to situations where the product itself was not new. The opinion explained that to be claimed as a product, the product "must be new as such, that is, regardless of the process or machine which makes it; and it must stand upon its own invention, again independently of the machine or process which makes it." *Id.* This was also the CCPA's view of product claims, providing the precedent carried forward to, and binding upon the Federal Circuit.<sup>5</sup>

### III

#### THE *EN BANC* RULING

Defying precedent, the *en banc* court adopts for all situations "the basic rule that the process terms limit product-by-process claims," maj. op. at 1293, whether the product is novel or known, and whether or not the new product could not have been fully described by its structure alone. The court eliminates the long-accepted expedient for new products whose structure is not fully known. While the *Scripps* decision is the only decision that is mentioned as "expressly overruled," maj. op. at 1293, *Scripps* is only one of many cases now discarded.

The *en banc* majority's response to the dissenters is to state that "the inventor is

absolutely free to use process steps to define this product" if its "structure is either not fully known or too complex to analyze," maj. op. at 1294, but to eliminate the premise that the inventor thereby obtains a product claim, not a process claim. According to the majority, a patentee can continue to obtain product claims using process descriptors, but such product claims are treated as process claims for infringement. The applicant would still have to demonstrate patentability of the new product as a product (independent of the process), while enforcement of the patent against an identical product would be limited to the infringer's use of the process steps used as a descriptor. For the first time, claims are construed differently for validity and for infringement.

It has been an inviolate rule that patent claims are construed the same way for validity and for infringement. See, e.g., *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed.Cir.2003) ("It is axiomatic that claims are construed the same way for both invalidity and infringement."); *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed.Cir.2001) ("Because the claims of a patent measure the invention at issue, the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses."); *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1363 (Fed.Cir.1998) ("Claims must be interpreted the same way for determining infringement as was done to sustain their validity."); *Southwall Technologies, Inc. v.*

5. There has been extensive commentary on this class of claim. See, e.g., Jon S. Saxe & Julian S. Levitt, *Product-by-Process Claims and Their Current Status in Chemical Patent Office Practice*, 42 J. Pat. Off. Soc'y 528, 559 (1960) ("Except in the chemical arts, a claim to a product must be in terms of the product's objective physical and chemical characteristics; but where these are unknown or impossible to express, a claim may define a product

in terms of the process by which it is made. This product-by-process exception is to be distinguished from the use of process terminology as descriptive of a state of being."); Brian S. Tomko, *Scripps or Atlantic: The Federal Circuit Squares Off Over the Scope of Product-by-Process Patents*, 60 Brook. L.Rev. 1693, 1696 (1995) (the *Atlantic* decision "pared the scope of a product-by-process patent to that of a glorified process patent").





it of today's complex science. The *en banc* court's ethical about "compound X, excess Y," is simply irrelevant we must resolve. Science it is often easier to show that things are the same, than to find chemical or biological structural differences. In the case at bar, X-ray diffraction patterns and spectra could show that the two are the same, although their exact nature is undefined. However, the court announces that the only way to decide whether the accused compound is the patented compound is to compare whether they were made by the same method. Maj. op. at 10. Analytical tools can be used to compare an infringer's compound with the patented compound, other than a comparison of the chemical structure and accused infringing compound. The question has many answers, but the court's answer is to be irrelevant.

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made by any process, by observing that the patentee had not shown how the infringing and patented products “can be recognized,” *id.* at 310, 4 S.Ct. 455, an aspect at the opposite pole from the case at bar, where the patentee provided elaborate details as to how the patented and accused crystal forms can be recognized.

The panel also states that “the applicant’s statement in the file wrapper that ‘the method of preparation . . . is not considered the heart of the present invention’ should not be afforded undue gravitas.” Maj. op. at 1296. This too is an aberration of precedent, and is contrary to the many rulings of the Supreme Court and this court that afford due gravitas to the applicant’s statement of what has been invented. See, e.g., *BASF*, 111 U.S. at 308, 4 S.Ct. 455 (“It is very plain that the specification of the original patent, No. 95,465, states the invention to be a process for preparing alizarine, not as a new substance prepared for the first time, but as the substance already known as alizarine, to be prepared, however, by the new process, which process is to be the subject of the patent. . . .”); *Plummer v. Sargent*, 120 U.S. at 443, 7 S.Ct. 640 (quoting specification of companion patent, where inventor stated “My invention consists in a process of covering iron with a very thin coating of oil, and then subjecting it to heat, the effect of which is to leave upon the iron a firm film, which is very durable, and gives the iron a highly ornamental appearance, like that of bronze”). The Federal Circuit’s emphasis on the importance of the specification has been repeatedly stated. E.g., *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed.Cir.2005) (*en banc*) (“[T]he specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” (internal quotation marks omitted)).

The *en banc* court appears to misjudge the implications of its ruling, for the court states that it is now making available to “others the right to freely practice process Z [a different process] that may produce a better product in a better way.” Maj. op. at 1294. If others can indeed make a better product, this expedient presents no impediment. That is not the issue of this case. The issue is the right to make the same product, by making a process change that does not change the product. By now assuring that right, the exclusionary value of the claim to a new product is lost.

The purpose of the rule of necessity is to allow inventors of complex new products to obtain the patent scope to which their invention is entitled—the scope of the novel product they invented, no more and no less. The majority's change of law simply imposes unfairness as well as legal error on patent-supported advances.

## SUMMARY

Precedent establishes that the correct construction of claims that recite process steps depends, like all claim construction, on what has been invented. No single rule fits all inventions. The construer must view the claims in light of the description of the invention in the specification, the prior art, and the prosecution history. In the complex law and practice of patents and inventions, the special expedient here of concern arises when the precise structure of a new product is not known from the information available when the patent application was filed. The law has enabled and endorsed this expedient of describing a product in order to claim it as a product, whereby validity and infringement are determined as a product, independent of any process term that was used to aid in defining the product. This expedient does not enlarge patent scope; it simply permits patenting what has been invented. A nar-

row but clear body of law has evolved to accommodate this need of complex technologies. This entire body of law is today overturned, *sua sponte* and without a hearing, without any participation of those affected, without identification of the intended benefits. I respectfully dissent from the *en banc* court's rulings, as well as the procedure by which they were reached.

LOURIE, Circuit Judge, dissenting from *en banc* Section III. A. 2.

I respectfully dissent from the court's *en banc* holding in Section III. A. 2 that product-by-process claims always require use of the recited process in order to be infringed.

I agree that there is substantial Supreme Court precedent that holds that product-by-process claims require use of the recited process for there to be infringement. However, many of those cases applied overly broad language to fact situations involving old products or used vague language that makes it difficult to determine whether the products were old or new. Clearly, however, when a product is old, a product-by-process claim cannot be interpreted as a claim to the product made by any means. The product is old and unpatentable *per se*. *BASF* in fact involved an old product. See *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293, 311, 4 S.Ct. 455, 28 L.Ed. 433 (1884) ("It was an old article.").

There is arguably a different situation that should apply to chemical-biological products today than to mechanical products of more than a century ago. When a product is new and the inventor claims it by a process of preparation, I fail to see why the product-by-process claim should not be interpreted as a product claim that can be infringed even when the product is made by means other than that recited in the claim. Supreme Court precedent dealing with old products, while utilizing broad

language, does not foreclose that possibility. The Court years ago did not have occasion to consider today's innovations or decide whether a distinction should be made between a new chemical-biological product and an old product made by a new process.

And there may be differing results depending upon the exact wording of a claim at issue. For example, a claim reading "when made by" might only be infringed when the recited process is used by the accused, as it is situational. On the other hand, a claim reading "obtainable by" refers to capability, so it might not require use of the process to infringe. "Obtained by" is ambiguous. Bright lines have their uses, but judging should take account of differing circumstances. In addition, of course, in order to sustain any claim for infringement, a patent owner must prove that an accused product is the same as that covered by an asserted claim. If the reason a product was claimed by its process was that its structure was unknown, then, if, at the time infringement is asserted, there still is no means to ascertain structurally whether the accused product is the same as that claimed, the infringement claim fails. However, that should not mean that a new product claimed by a process of preparation cannot ever be infringed when made by another process.

It may be that with today's analytical techniques there is little need for product-by-process claims. After all, claim 1 of the Abbott patent is a claim to a compound, not only by name, but also by certain of its characteristics. A claim to a product defined by its characteristics or properties surely is a proper claim.

However, product-by-process issues still seem to come before us and I would make a distinction between old products and new products in interpreting product-by-pro-

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may be differing results determine exact wording of a claim. For example, a claim reading "might only be infringed" and "process is used by the" is situational. On the other hand, reading "obtainable by" requires, so it might not require a process to infringe. "Obtained as" is. Bright lines have their uses. Bright lines should take account of circumstances. In addition, of course, to sustain any claim for patent infringement, the patent owner must prove that the product is the same as the asserted claim. If the product was claimed by its process and the structure was unknown, then infringement is asserted. There is no means to ascertain whether the accused product that claimed, the infringement. However, that should be a new product claimed by a process cannot ever be made by another process.

As with today's analytical methods, there is little need for product claims. After all, claim 1 of the patent is a claim to a compound, not a process, but also by certain of its characteristics. A claim to a product characterized by characteristics or properties is a claim.

Product-by-process issues still trouble us and I would make a distinction between old products and new products interpreting product-by-process

claims. Accordingly, I respectfully dissent from the court's en banc holding.



**EPISTAR CORPORATION, Appellant,**

**v.**

**INTERNATIONAL TRADE  
COMMISSION,  
Appellee,**

**and**

**Philips Lumileds Lighting Company,  
LLC, Intervenor.**

**No. 2007-1457.**

United States Court of Appeals,  
Federal Circuit.

May 22, 2009.

**Background:** Patent owner filed suit in United States International Trade Commission (ITC) to prevent importation of certain high-brightness light emitting diodes (LEDs) and products into United States, sale for importation, and sale within United States after importation, due to infringement of claims of patent. ITC found that foreign manufacturer infringed patent on surface-emitting LED and issued limited exclusion order (LEO) prohibiting importation of manufacturer's downstream LED products, regardless of manufacturer or importer of those products. Manufacturer petitioned for judicial review.

**Holdings:** The Court of Appeals, Rader, Circuit Judge, held that:

- (1) owner could not fortuitously gain rights against acquiring manufacturer due to merger that it did not have pre-merger;
- (2) applicant did not disclaim use of indium-tin oxide (ITO) in window layer of patent that kept opaque "metal electrical contact" but added "transparent

window layer" beneath it by making statement in background section of application that use of ITO was not "completely satisfactory" as front contact;

- (3) single, passing reference to ITO in specification as relatively unsatisfactory transparent electrical contact did not disavow use of ITO as transparent window layer;
- (4) specification did not need to make further enabling disclosures about its prior art uses to be construed to encompass ITO in transparent window layer;
- (5) term, "substrate," could include one or more layers of "supporting material" for active LED layers; and
- (6) ITC lacked statutory authority to issue LEO that excluded imported products by entities not named as respondents before ITC.

Affirmed in part, reversed in part, and remanded.

#### 1. Customs Duties $\S$ 85(3)

Summary determinations by the United States International Trade Commission (ITC) are reviewed without deference as a question of law.

#### 2. Customs Duties $\S$ 85(1)

Interpretation of settlement agreement between competitor and patent owner by United States International Trade Commission (ITC) in lawsuit regarding unfair practices in import trade was reviewable by Court of Appeals as question of state law. Tariff Act of 1930,  $\S$  337, 19 U.S.C.A.  $\S$  1337.

#### 3. Appeal and Error $\S$ 842(8)

Under California state law, contracts are interpreted without deference on appeal.